

# **Agenda for Quarterly Meeting on MDUFA IV (FY 2018-2022) Performance**

**June 20, 2019, 10:00 – 11:00**

**WebEx**

## **Welcome**

## **Guidance Development**

- Software Guidance Update

## **FDA MDUFA Performance — Actions through March 31, 2019**

- Report on decision goals for 2<sup>nd</sup> Quarter FY 2019.

## **Qualitative Update on Finances – 2<sup>nd</sup> Quarter FY 2019**

- User fee receipts through the 2<sup>nd</sup> Quarter FY 2019.
- Number of discretionary fee waivers or reductions granted by type of submission.

## **CDRH Registration and Listing**

- Report on registration and listing.

## **CDRH Training Update**

**Reminder:** Set date for 3<sup>rd</sup> Quarter 2019 meeting

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## Medical Devices

### Guidance Documents

Pursuant to the MDUFA IV Commitment Letter,<sup>1</sup> the table below includes all FDA guidance documents issued in the specified quarter related to the devices program. Pursuant to section 738A(a)(1)(A)(iii) of the FD&C Act, guidance documents that are related to the process for the review of devices and whether they are required by statute or are being issued pursuant to the MDUFA IV Commitment Letter are indicated as such. The table also indicates whether a guidance document is on the Center for Devices and Radiological Health's annual agenda of guidance documents (known as the A/B List).<sup>2</sup>

**Table 1: Draft and Final Guidance Documents Related to the Devices Program for FY 2019**

#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
1	Q1	Content of Premarket Submissions for Management of Cybersecurity in Medical Devices - Draft Guidance for Industry and Food and Drug Administration Staff <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM623529">www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM623529</a>	10/18/2018	Yes	No	N/A	A-List
2	Q1	Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices and Certain Devices Requiring Direct Marking - Immediately in Effect Guidance for Industry and Food and Drug Administration Staff <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM592340">www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM592340</a>	11/05/2018	No	No	N/A	A-List
3	Q1	Recommendations for Dual 510(k) and CLIA Waiver by Application Studies - Draft Guidance for Industry and Food and Drug Administration Staff <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM586502">www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM586502</a>	11/29/2018	No <sup>3</sup>	No	N/A	A-List

<sup>1</sup> [www.fda.gov/downloads/ForIndustry/UserFees/MedicalDeviceUserFee/UCM535548.pdf](http://www.fda.gov/downloads/ForIndustry/UserFees/MedicalDeviceUserFee/UCM535548.pdf); see section VI (Performance Reports)

<sup>2</sup> [www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm580172.htm](http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm580172.htm)

<sup>3</sup> CDRH policy is to say 'no' unless the guidance document is 100% (or almost 100%) related to the process for the review of device applications. The CLIA aspects of this guidance are not related, whereas the 510(k) aspects are.

#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
4	Q1	Select Updates for Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices - Draft Guidance for Industry and Food and Drug Administration Staff <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM586506">www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM586506</a>	11/29/2018	No	Yes	Sec. 3057 of the 21st Century Cures Act	A-List
5	Q1	Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use - Draft Guidance for Industry and Food and Drug Administration Staff <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM626742">www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM626742</a>	11/30/2018	Yes	No	N/A	A-List
6	Q1	Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use - Draft Guidance for Industry and Food and Drug Administration Staff <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM626743">www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM626743</a>	11/30/2018	Yes	No	N/A	A-List
7	Q1	User Fees and Refunds for Premarket Approval Applications and Device Biologics License Applications - Guidance for Industry and Food and Drug Administration Staff <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM345633">www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM345633</a>	12/12/2018	Yes	No	N/A	A-List
8	Q1	Manufacturing Site Change Supplements: Content and Submission - Final Guidance for Industry and Food and Drug Administration Staff <a href="http://www.fda.gov/media/124387/download">www.fda.gov/media/124387/download</a>	12/17/2018	Yes	No	N/A	A-List
9	Q1	Breakthrough Devices Program - Guidance for Industry and Food and Drug Administration Staff <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM581664">www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM581664</a>	12/18/2018	Yes	Yes	Sec. 3051 of the 21st Century Cures Act (Sec. 515B(f) of the FD&C Act)	A-List
10	Q2	Coordinated Development of Antimicrobial Drugs and Antimicrobial Susceptibility Test Devices - Guidance for Industry and Food and Drug Administration Staff <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM521421">www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM521421</a>	2/1/2019	Yes	No	N/A	A-List

#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
11	Q2	Safety and Performance Based Pathway - Guidance for Industry and Food and Drug Administration <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM604195">www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM604195</a>	2/1/2019	Yes	No	N/A	A-List
12	Q2	The Least Burdensome Provisions: Concept and Principles - Guidance for Industry and FDA Staff <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM085999">www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM085999</a>	2/5/2019	No <sup>3</sup>	No	N/A	A-List
13	Q2	Principles of Premarket Pathways for Combination Products Draft Guidance for Industry and FDA Staff <a href="http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM630458.pdf">www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM630458.pdf</a>	2/6/2019	No <sup>3</sup>	No	N/A	N/A
14	Q2	Intent to Exempt Certain Unclassified Medical Devices from Premarket Notification Requirements - Guidance for Industry and Food and Drug Administration Staff <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM407292">www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM407292</a>	2/8/2019	Yes	No	N/A	N/A
15	Q2	Evaluation of Devices Used with Regenerative Medicine Advanced Therapies; Guidance for Industry <a href="http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/CellularandGeneTherapy/UCM585417">www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/CellularandGeneTherapy/UCM585417</a>	2/15/2019	Yes	Yes	Sec. 3034 of the 21st Century Cures Act	N/A
16	Q2	Nonbinding Feedback After Certain Food and Drug Administration Inspections of Device Establishments - Draft Guidance for Industry and Food and Drug Administration Staff <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM631397">www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM631397</a>	2/19/2019	No	Yes	Sec. 702 of FDARA (Sec. 704 of the FD&C Act)	A-List
17	Q2	Implanted Brain-Computer Interface (BCI) Devices for Patients with Paralysis or Amputation - Non-clinical Testing and Clinical Considerations - Draft Guidance for Industry and Food and Drug Administration Staff <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM631786">www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM631786</a>	2/25/2019	Yes	No	N/A	B-List
18	Q2	Refuse to Accept Policy for 510(k)s - Guidance for Industry and Food and Drug Administration Staff <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014">www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014</a>	2/25/2019	Yes	No	N/A	N/A

#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
19	Q2	Acceptance and Filing Reviews for Premarket Approval Applications (PMAs) - Guidance for Industry and Food and Drug Administration Staff <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313368">www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313368</a>	2/25/2019	Yes	No	N/A	N/A
20	Q2	Release of ORA Laboratory Analytical Results to the Responsible Party: Guidance for FDA Staff <a href="http://www.fda.gov/RegulatoryInformation/Guidances/UCM633645">www.fda.gov/RegulatoryInformation/Guidances/UCM633645</a>	3/1/2019	No	No	N/A	N/A
21	Q2	Medical Devices Containing Materials Derived from Animal Sources (Except for In Vitro Diagnostic Devices) - Guidance for Industry and Food and Drug Administration Staff <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM381491">www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM381491</a>	3/15/2019	Yes	No	N/A	N/A
22	Q2	Review and Update of Device Establishment Inspection Processes and Standards Draft Guidance <a href="http://www.fda.gov/RegulatoryInformation/Guidances/UCM634774">www.fda.gov/RegulatoryInformation/Guidances/UCM634774</a>	3/29/2019	No	Yes	Sec. 702 of FDARA (Sec. 704 of the FD&C Act)	N/A

**Quarterly Update on  
Medical Device Performance Goals  
----MDUFA IV CDRH Performance Data ----  
Action through 31 March 2019**

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## Acronyms and Abbreviations

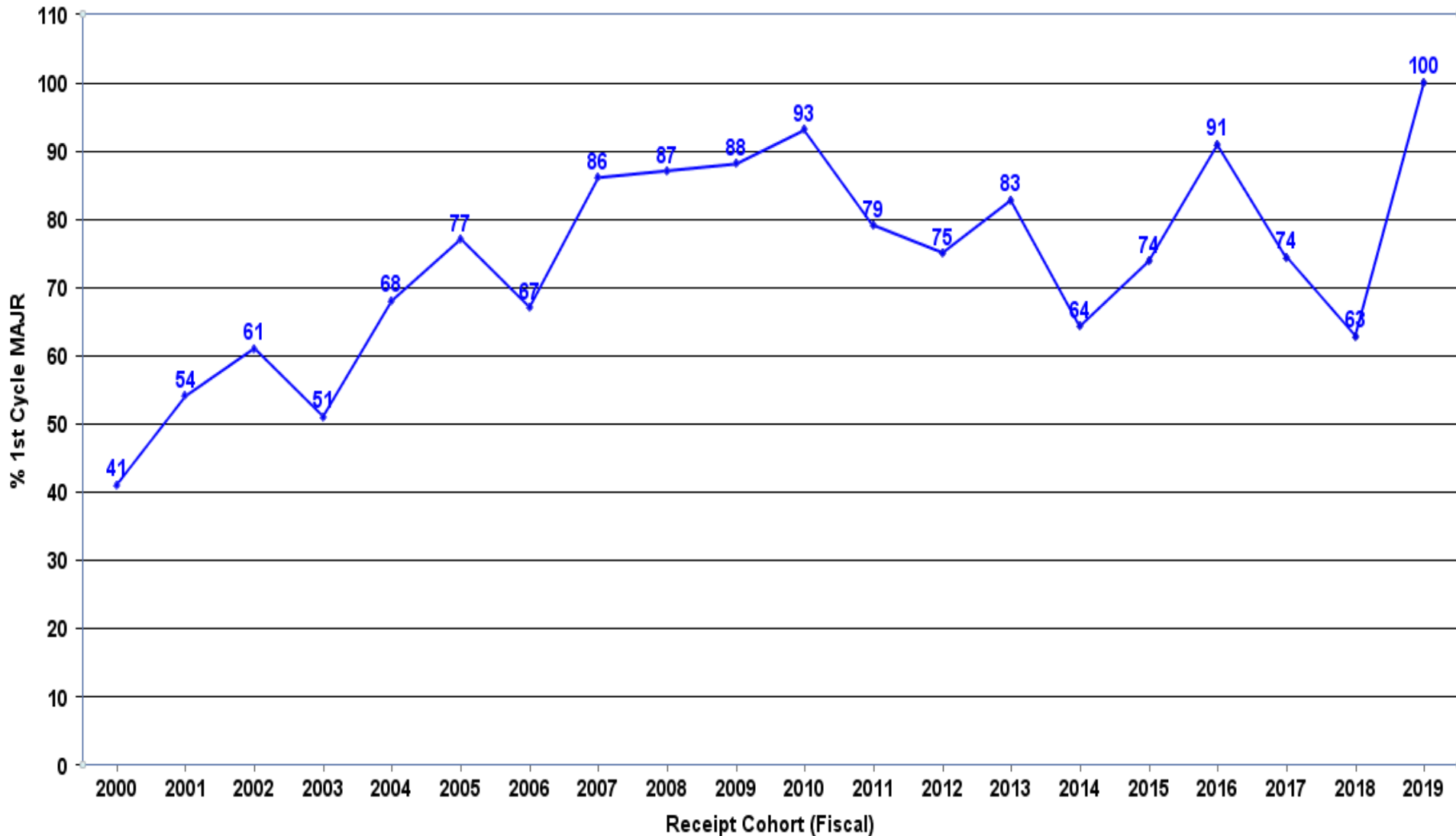
510(k)	Premarket Notification
CDRH	Center for Devices and Radiologic Health
CLIA	Clinical Laboratory Improvement Amendments
DAGRID	Division of Anesthesiology, General Hospital, Respiratory, Infection Control, and Dental Devices
DCD	Division of Cardiovascular Devices
DCTD	Division of Chemistry and Toxicology Devices
DIHD	Division of Immunology and Hematology Devices
DMD	Division of Microbiology Devices
DMGP	Division of Molecular Genetics and Pathology
DNPMD	Division of Neurological and Physical Medicine Devices
DOD	Division of Orthopedic Devices
DOED	Division of Ophthalmic and Ear, Nose and Throat Devices
DRGUD	Division of Reproductive, Gastro-Renal, and Urological Devices
DRH	Division of Radiological Health
DSD	Division of Surgical Devices
IDE	Investigational Device Exemption
IVD	In Vitro Diagnostic
LDT	Laboratory Developed Test
MDUFA	Medical Device User Fee Act
NSE	Not Substantially Equivalent
ODE	Office of Device Evaluation
OIR	Office of In Vitro Diagnostics and Radiological Health
PMA	Premarket Application
RTA	Refuse to Accept
RTF	Refuse to File
SE	Substantially Equivalent
SI	Substantive Interaction

**Note: Data may change in subsequent quarterly and annual reports.**

PMA<sub>s</sub>

Q2FY19

# PMA Originals Filed As Of 12/31/18: 1st Cycle Major Deficiency Rate as of 3/31/19

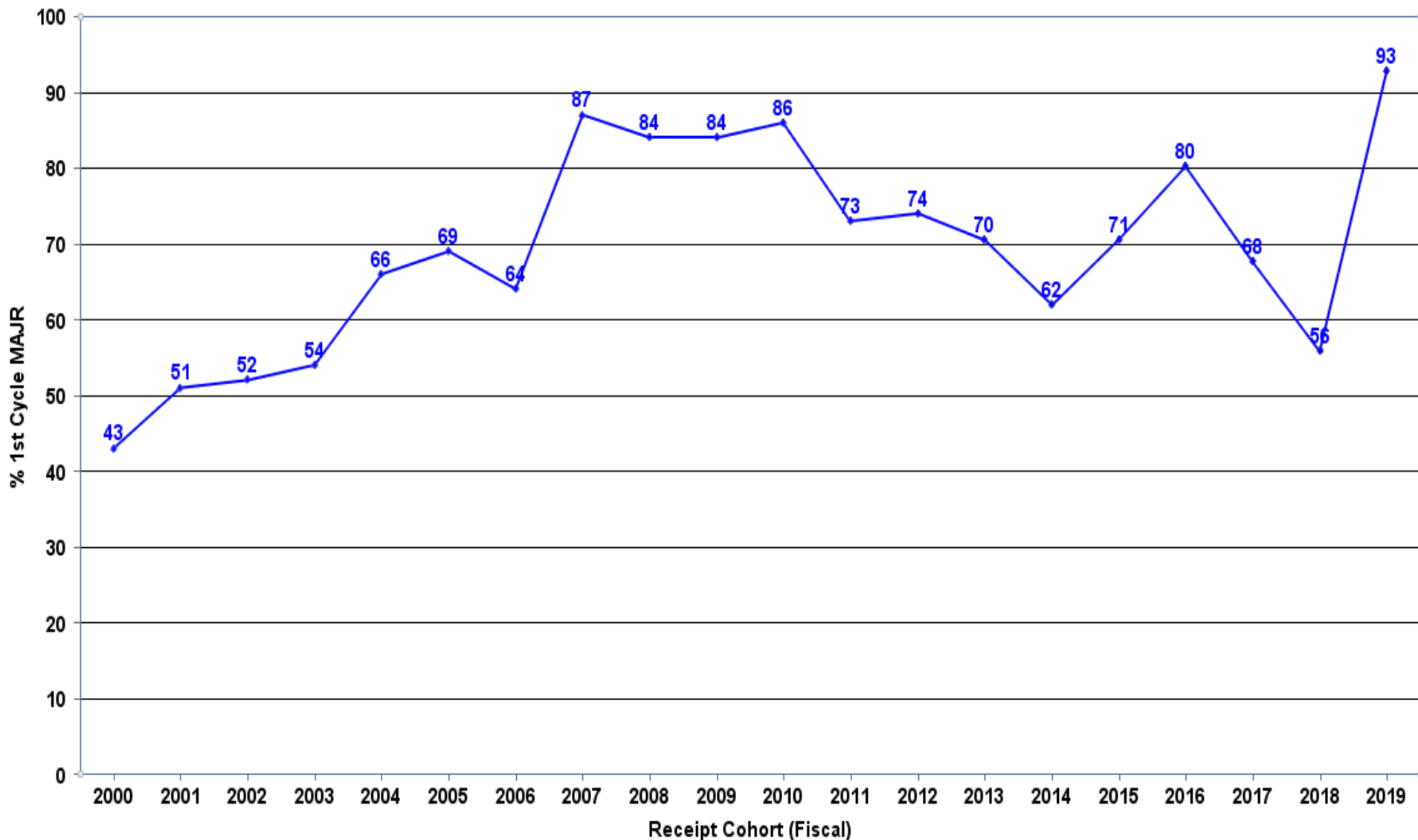


Data are based upon the number of submissions that received a major deficiency letter on the 1st review cycle, calculated as a percentage of the number of submissions with a completed 1st review cycle, for submissions rec'd, accepted & filed as of 12/31/18. Note: For the current FY, a Proceed Interactively decision is considered a completed 1st cycle.

◆ % 1st Cycle MAJR PMAO

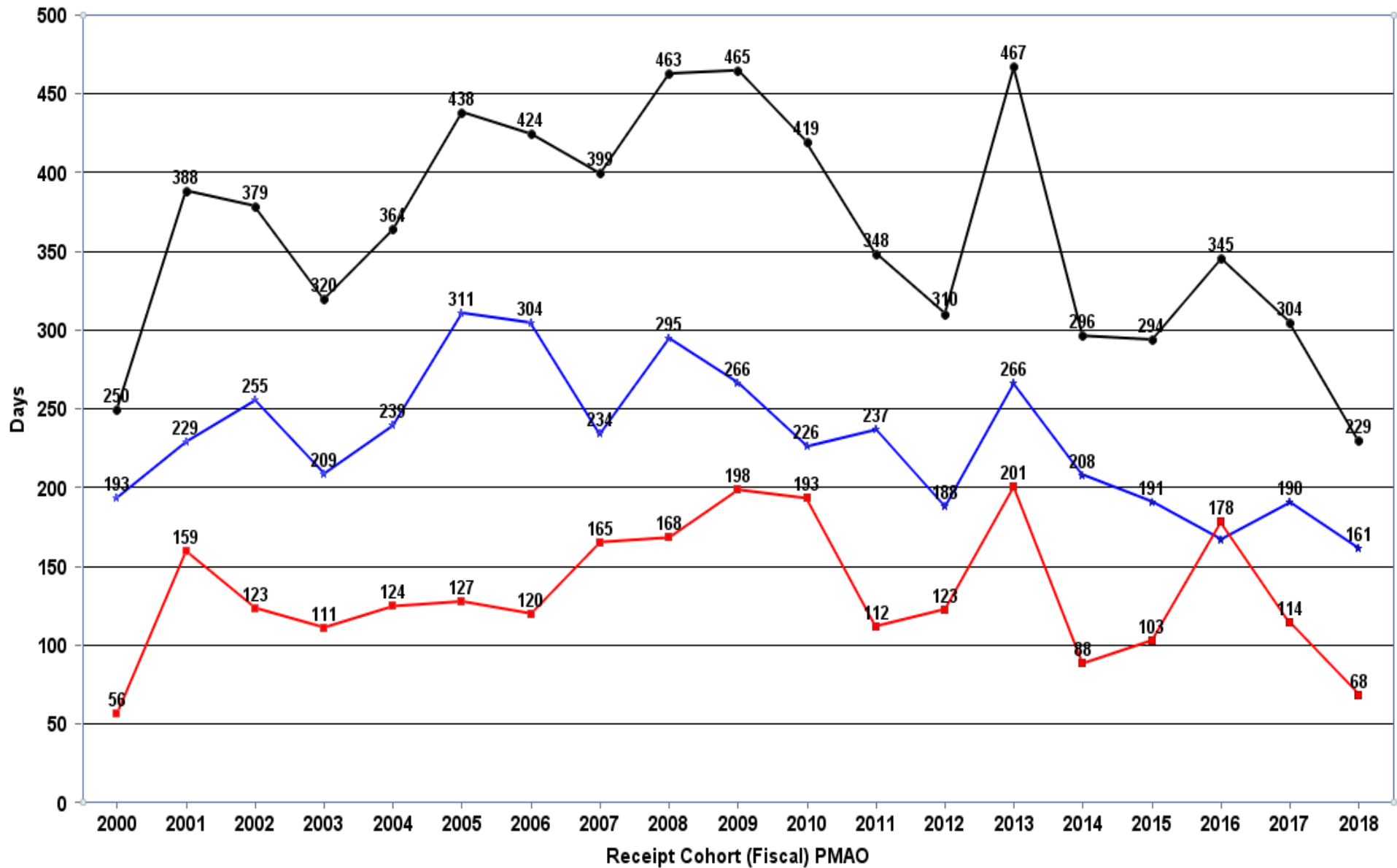


# PMA Originals and Panel Track Supplements Filed As Of 12/31/18: 1st Cycle Major Deficiency Rate as of 3/31/19



Data are based upon the number of submissions that received a major deficiency letter on the 1st review cycle, calculated as a percentage of the number of submissions with a completed 1st review cycle, for submissions rec'd, accepted & filed as of 12/31/18. Note: For the current FY, a Proceed Interactively decision is considered a completed 1st cycle.

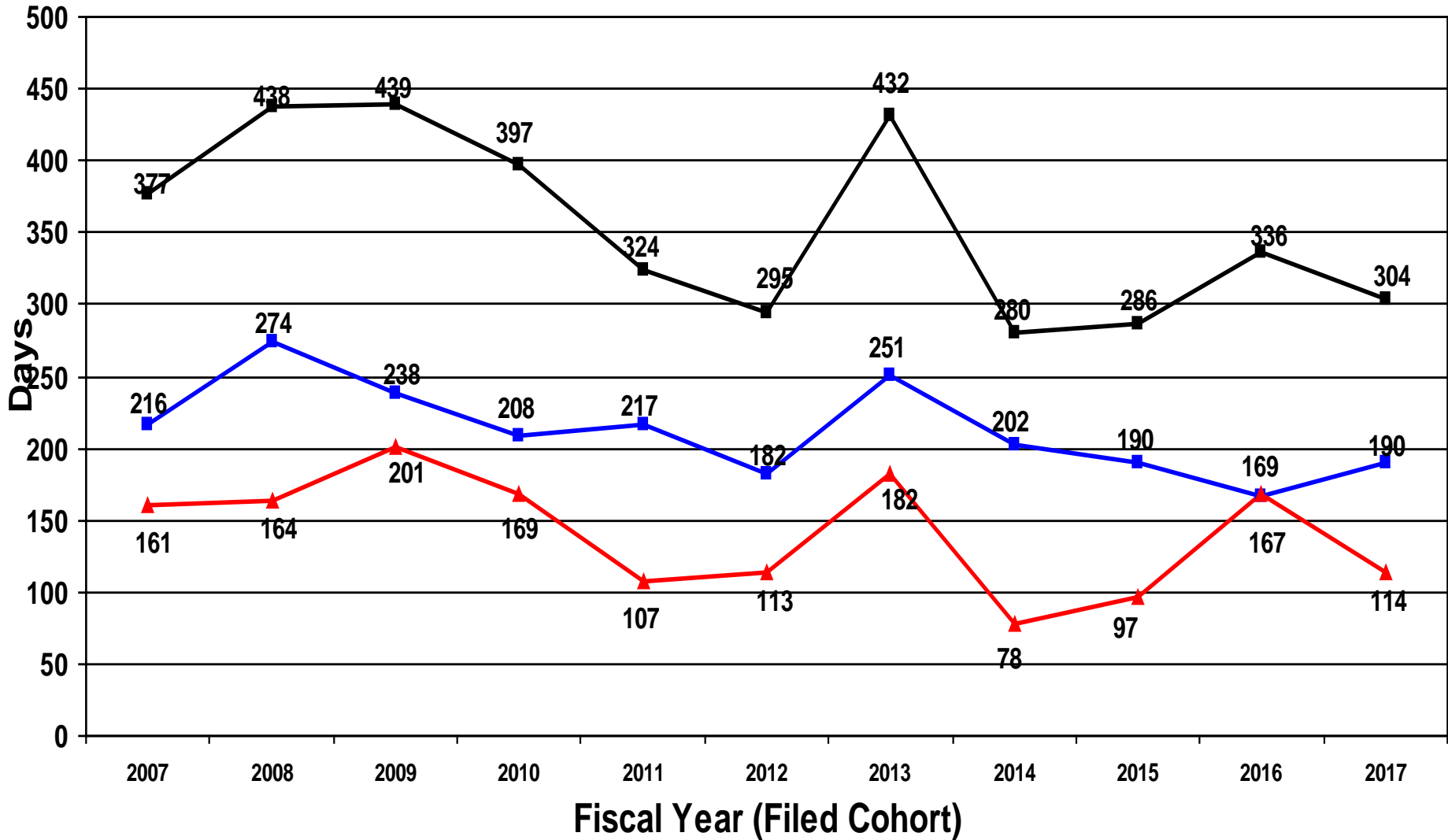
### PMA Originals Filed As Of 2019/03/31: Average Time to MDUFA Decision



Cohorts not yet closed: 2017: 97.44%; 2018: 62.79%

★ Avg FDA Days PMAO ■ Avg Applicant Days PMAO ● Avg Total Days PMAO

# PMA Originals Filed as of 03/31/2019: Average Time to MDUFA Decision Comparison of Cohorts at 97.4% Closure

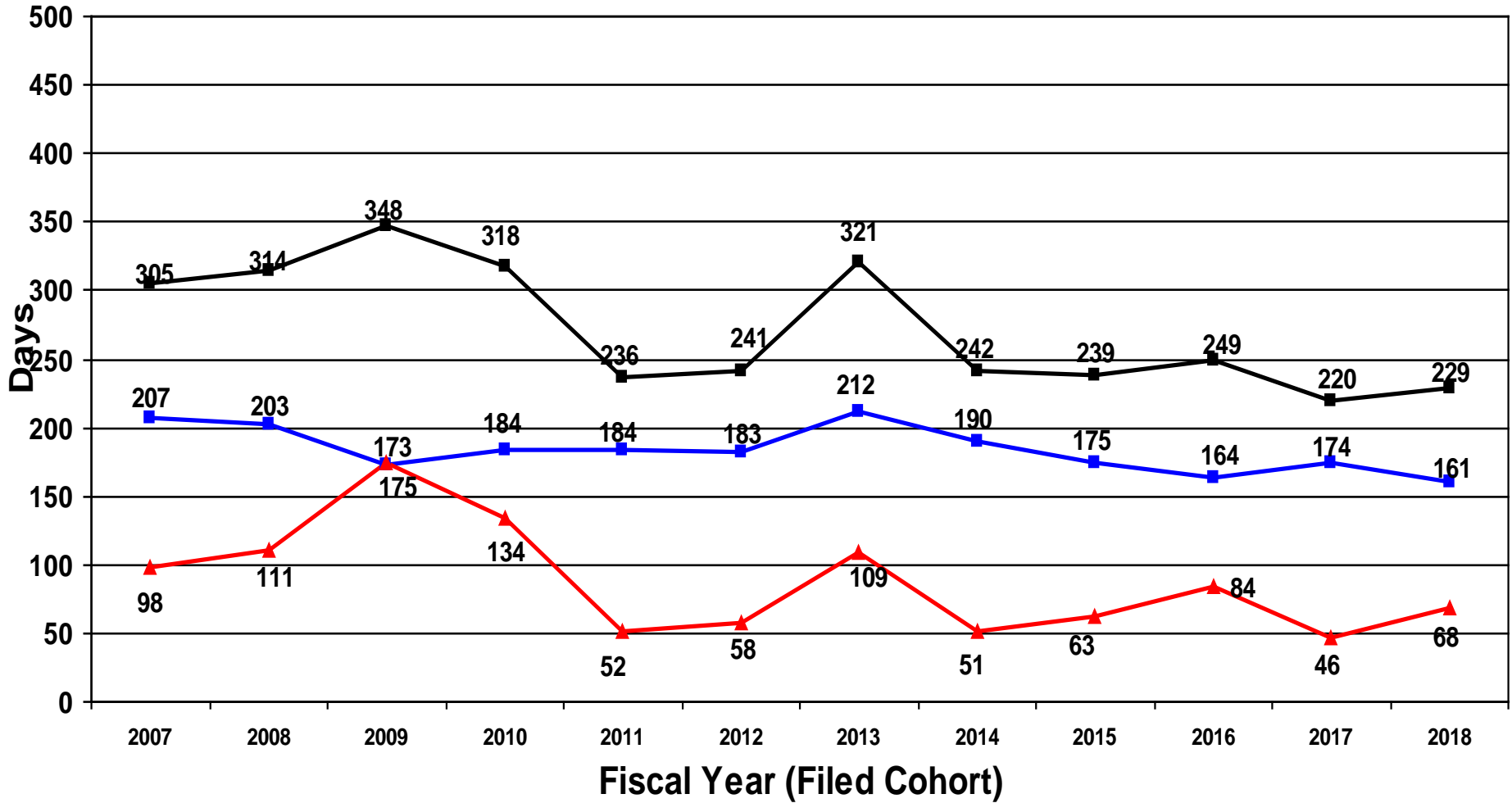


■ Avg Total Days PMAO

■ Avg FDA Days PMAO

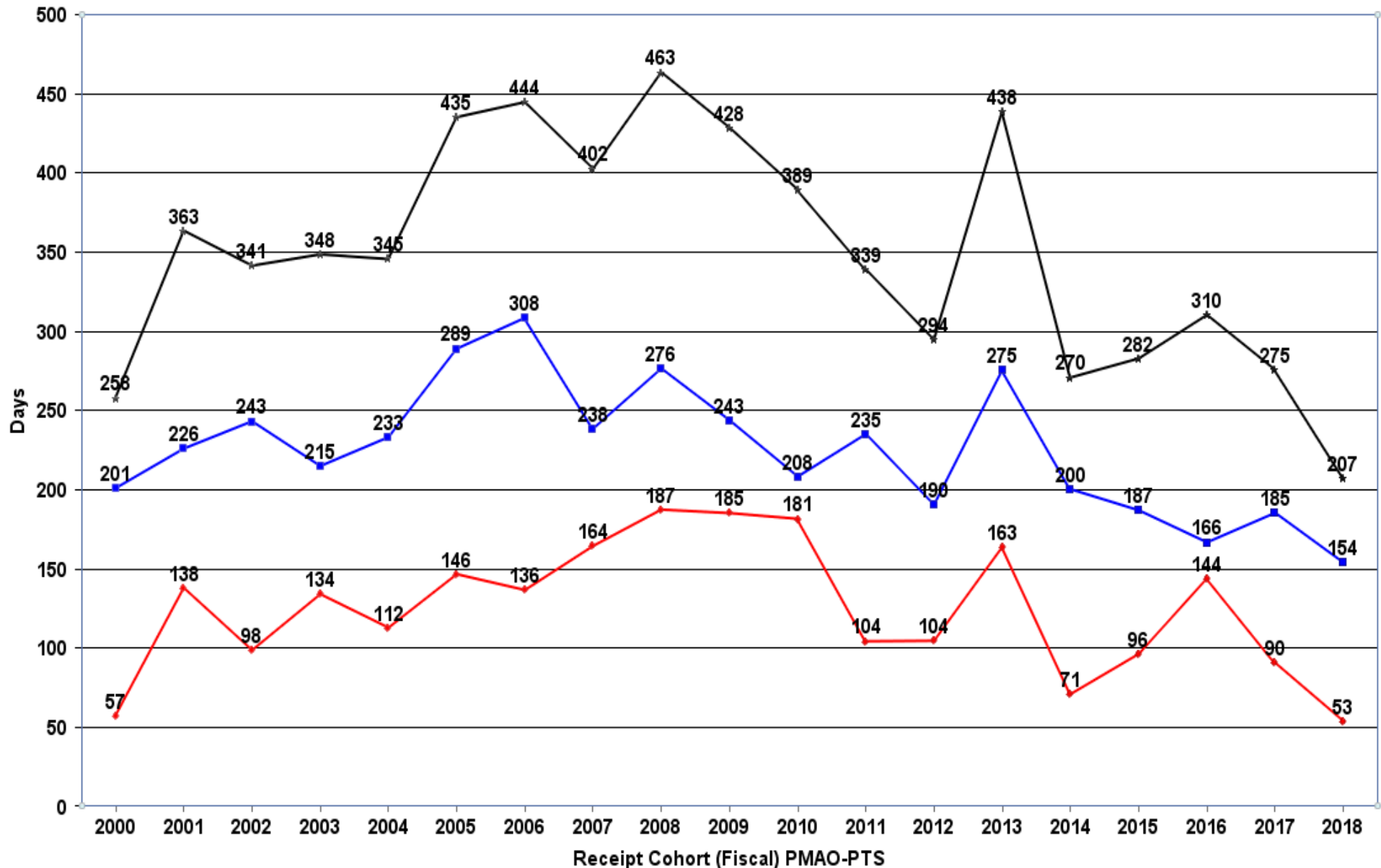
▲ Avg Applicant Days PMAO

# PMA Originals Filed as of 03/31/2019: Average Time to MDUFA Decision Comparison of Cohorts at 62.8% Closure



Avg Total Days PMAO     
  Avg FDA Days PMAO     
  Avg Applicant Days PMAO

# PMA Originals and Panel Track Supplements Filed As Of 2019/03/31: Average Time to MDUFA Decision

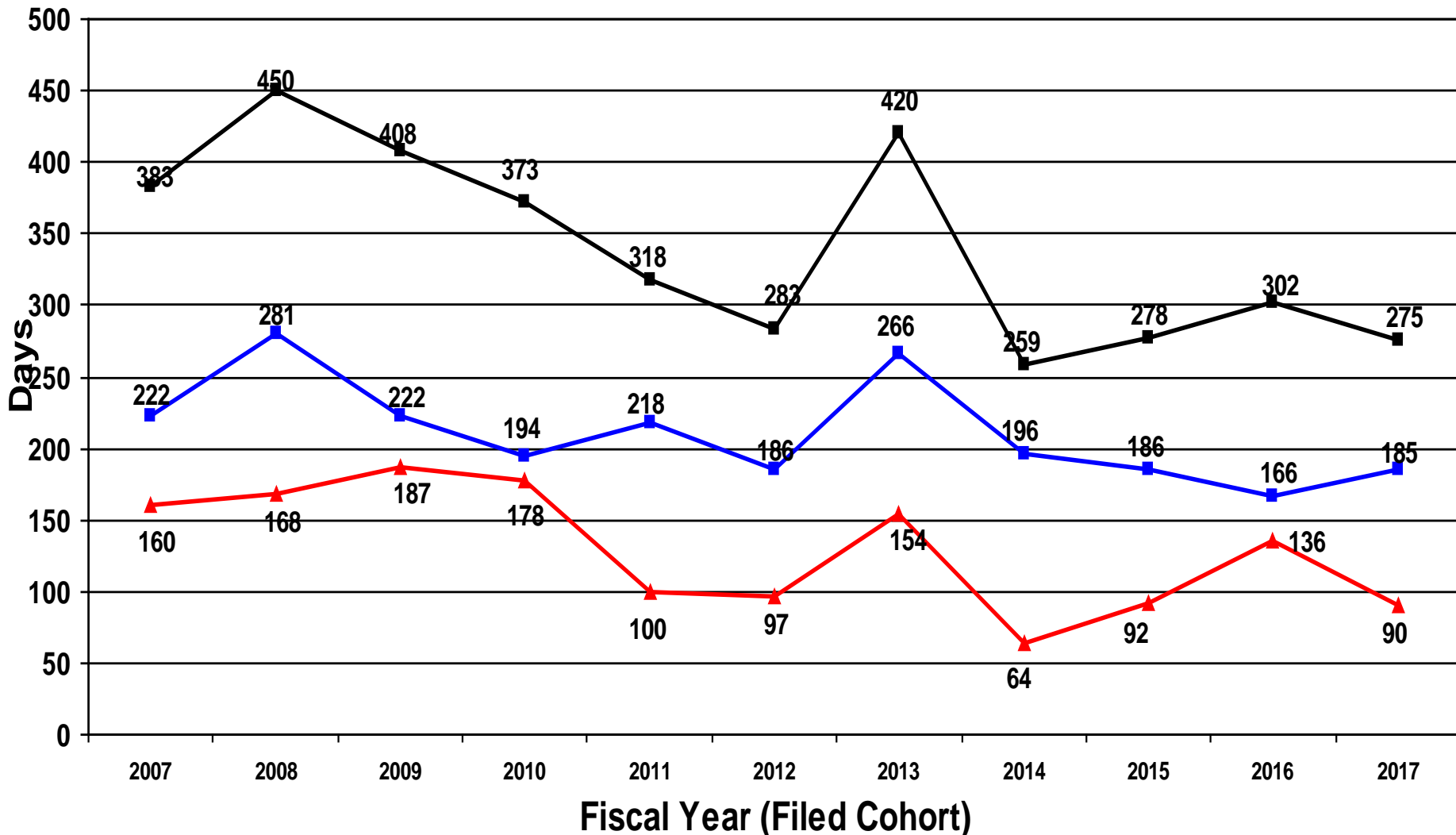


Cohorts not yet closed: 2017: 98.46%; 2018: 70.59%

■ Avg FDA Days PMAO-PTS ◆ Avg Applicant Days PMAO-PTS ★ Avg Total Days PMAO-PTS

# PMA Originals and Panel Track Supplements Filed as of 03/31/2019: Average Time to MDUFA Decision

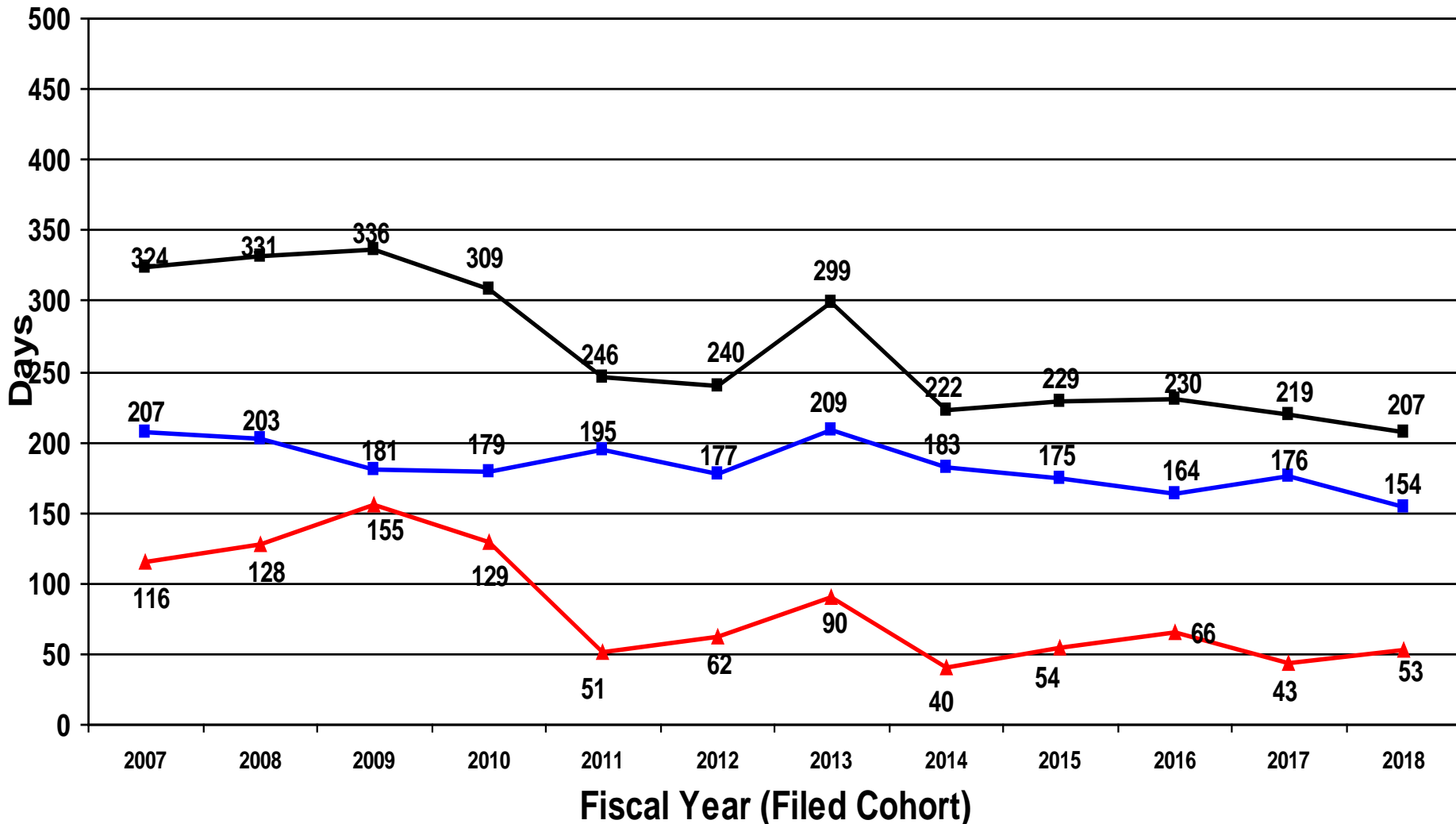
## Comparison of Cohorts at 98.5% Closure



■ Avg Total Days PMAO-PTS     
 ■ Avg FDA Days PMAO-PTS     
 ▲ Avg Applicant Days PMAO-PTS

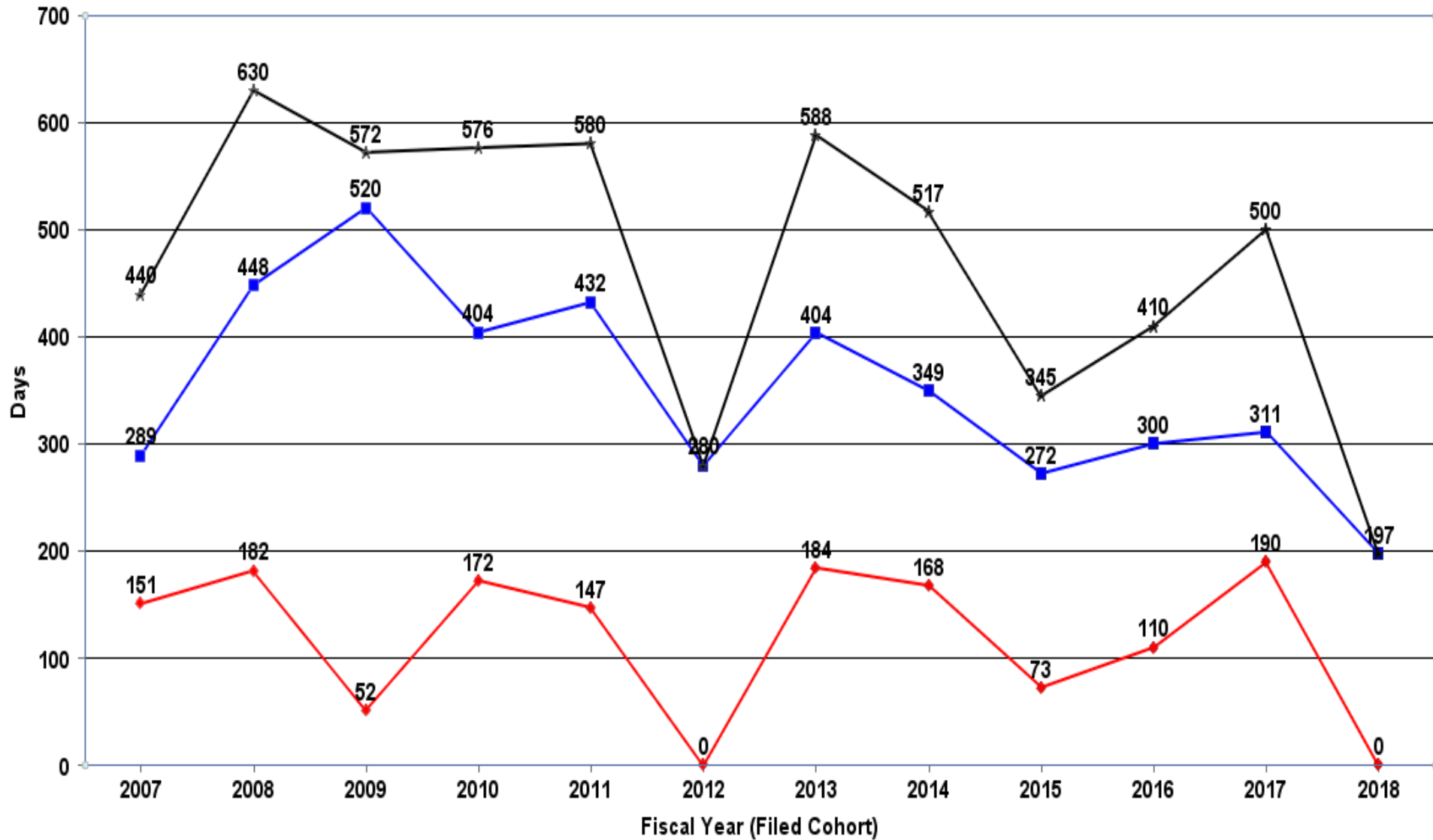
# PMA Originals and Panel Track Supplements Filed as of 03/31/2019: Average Time to MDUFA Decision

## Comparison of Cohorts at 70.6% Closure



■ Avg Total Days PMAO-PTS     
 ■ Avg FDA Days PMAO-PTS     
 ▲ Avg Applicant Days PMAO-PTS

PMA Originals With Panel Review: Average Time to MDUFA Decision for Submissions Filed As Of: 2019/03/31

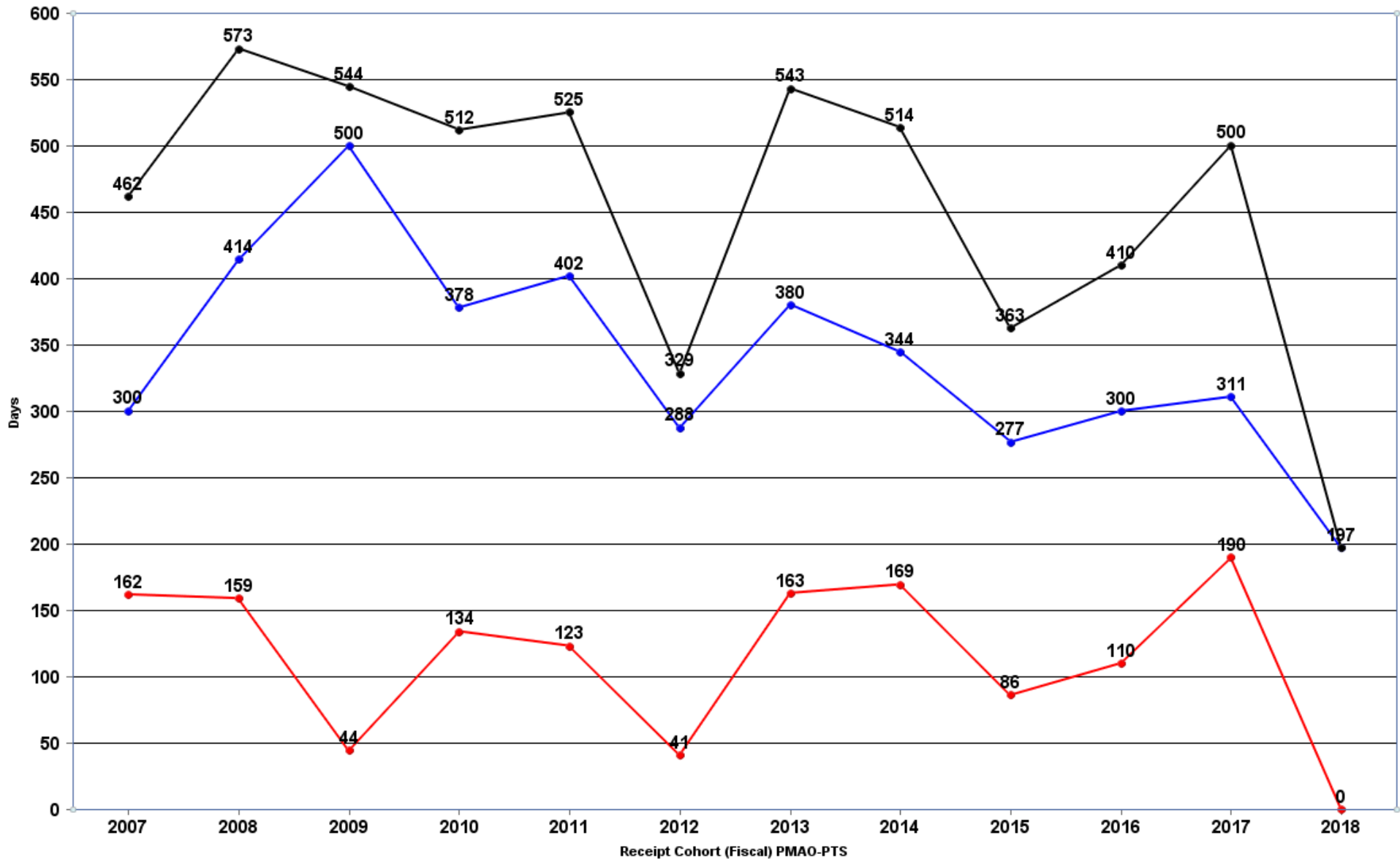


Numbers Filed: 2007 = 7; 2008 = 7; 2009 = 6; 2010 = 7; 2011 = 11; 2012 = 1; 2013 = 11; 2014 = 5; 2015 = 5; 2016 = 1; 2017 = 5; 2018 = 4

■ Avg FDA Days to MDUFA Decision PMAO ♦ Avg MFR Days to MDUFA Decision PMAO ★ Avg Total Days to MDUFA Decision PMAO



PMA Originals and Panel Track Supplements With Panel Review: Average Time to MDUFA Decision for Submissions Filed As Of: 2019/03/31



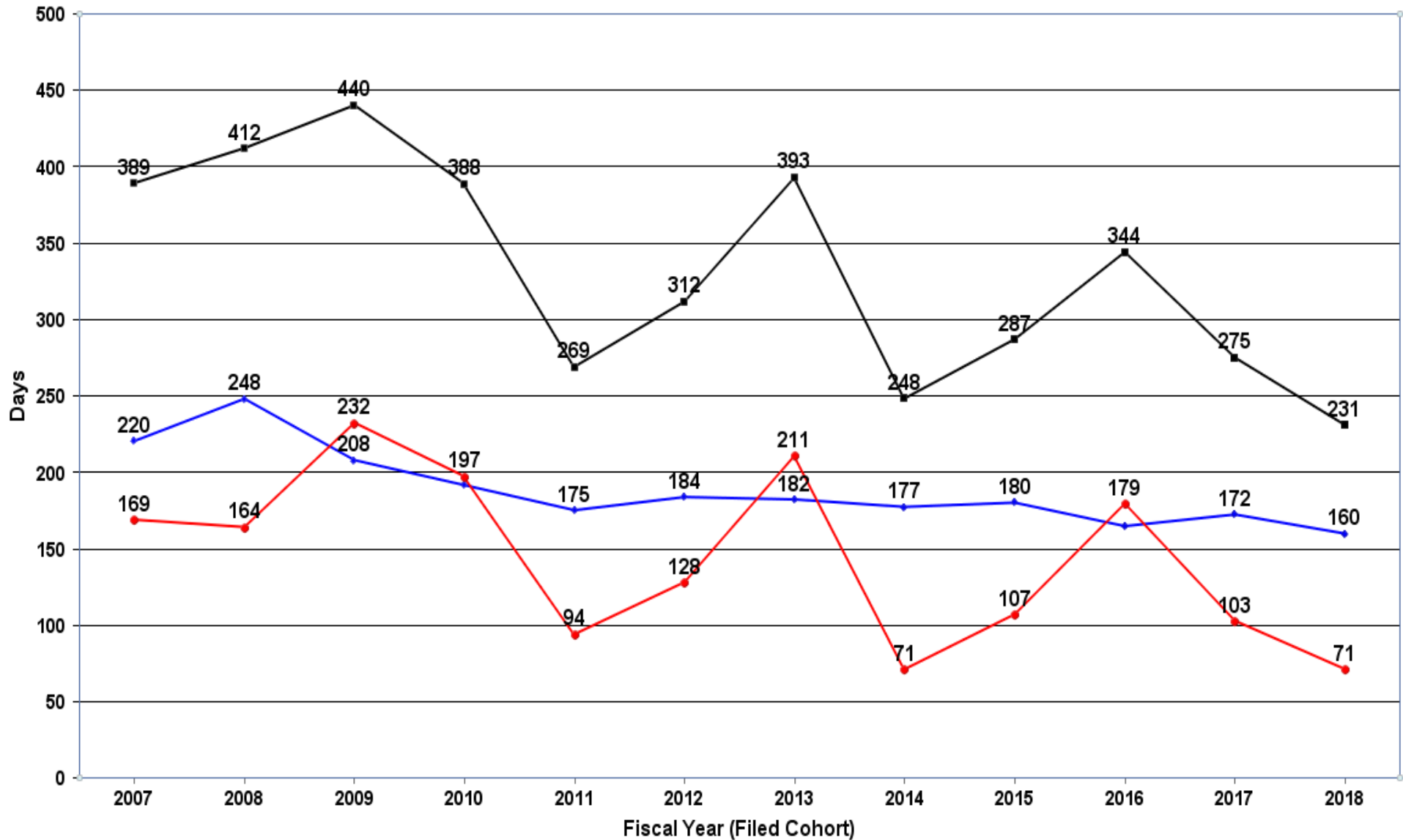
Numbers Filed: 2007 = 8; 2008 = 8; 2009 = 7; 2010 = 9; 2011 = 14; 2012 = 2; 2013 = 17; 2014 = 6; 2015 = 6; 2016 = 1; 2017 = 5; 2018 = 4

● Avg FDA Days to MDUFA Decision PMAO-PTS ● Avg MFR Days to MDUFA Decision PMAO-PTS ● Avg Total Days to MDUFA Decision PMAO-PTS

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Performance data from FY13 onward map to Table 1.8. Numbers filed map to table 1.6.

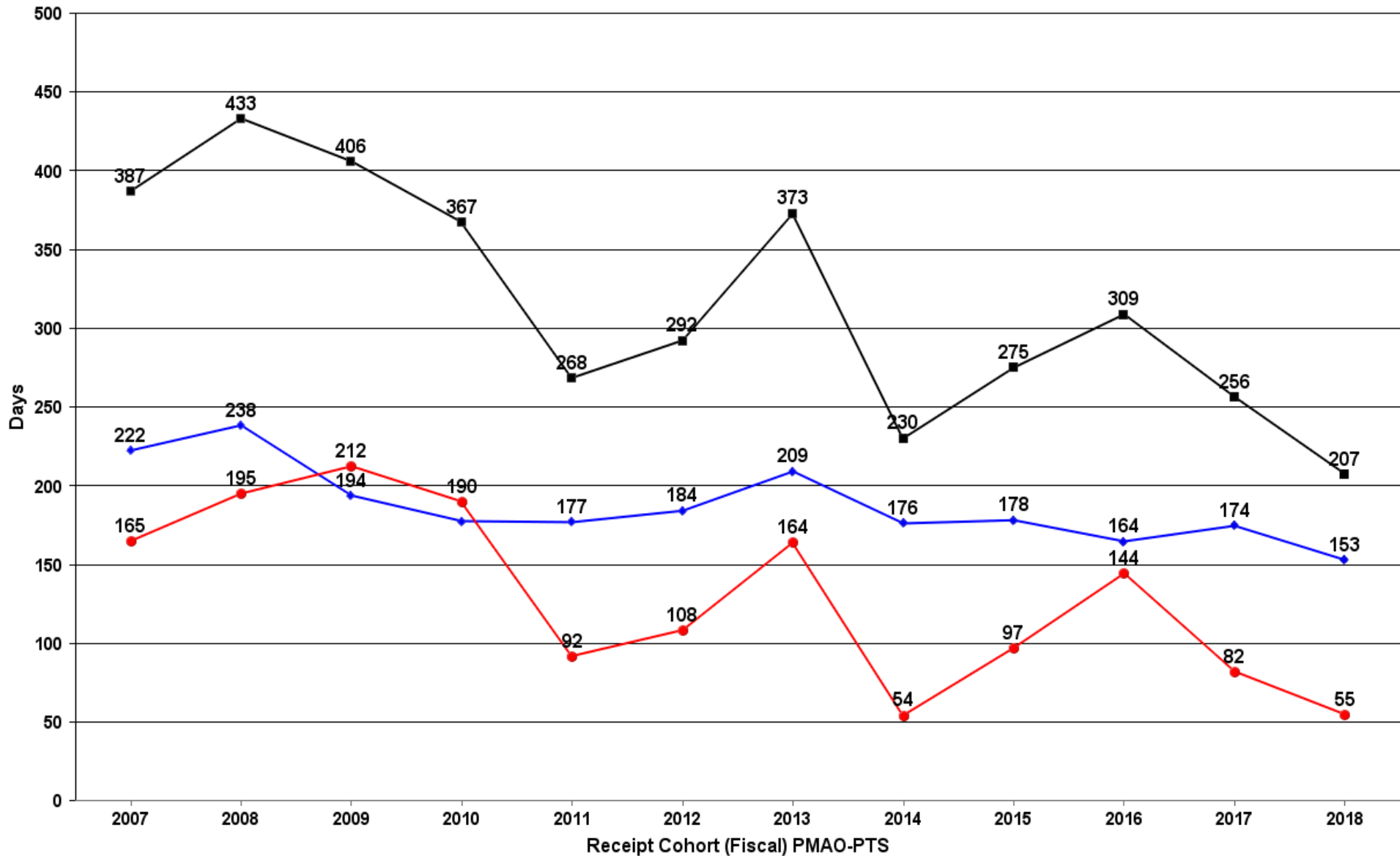
PMA Originals: Average Time to MDUFA Decision for Submissions Without Panel Review Filed as of 2019/03/31



Numbers Filed: 2007 = 28; 2008 = 23; 2009 = 26; 2010 = 36; 2011 = 32; 2012 = 23; 2013 = 18; 2014 = 23; 2015 = 37; 2016 = 54; 2017 = 34; 2018 = 39

◆ Avg FDA Days to MDUFA Decision PMAO ● Avg MFR Days to MDUFA Decision PMAO ■ Avg Total Days to MDUFA Decision PMAO

PMA Originals and Panel Track Supplements: Average Time to MDUFA Decision for Submissions Without Panel Review Filed as of 2019/03/31

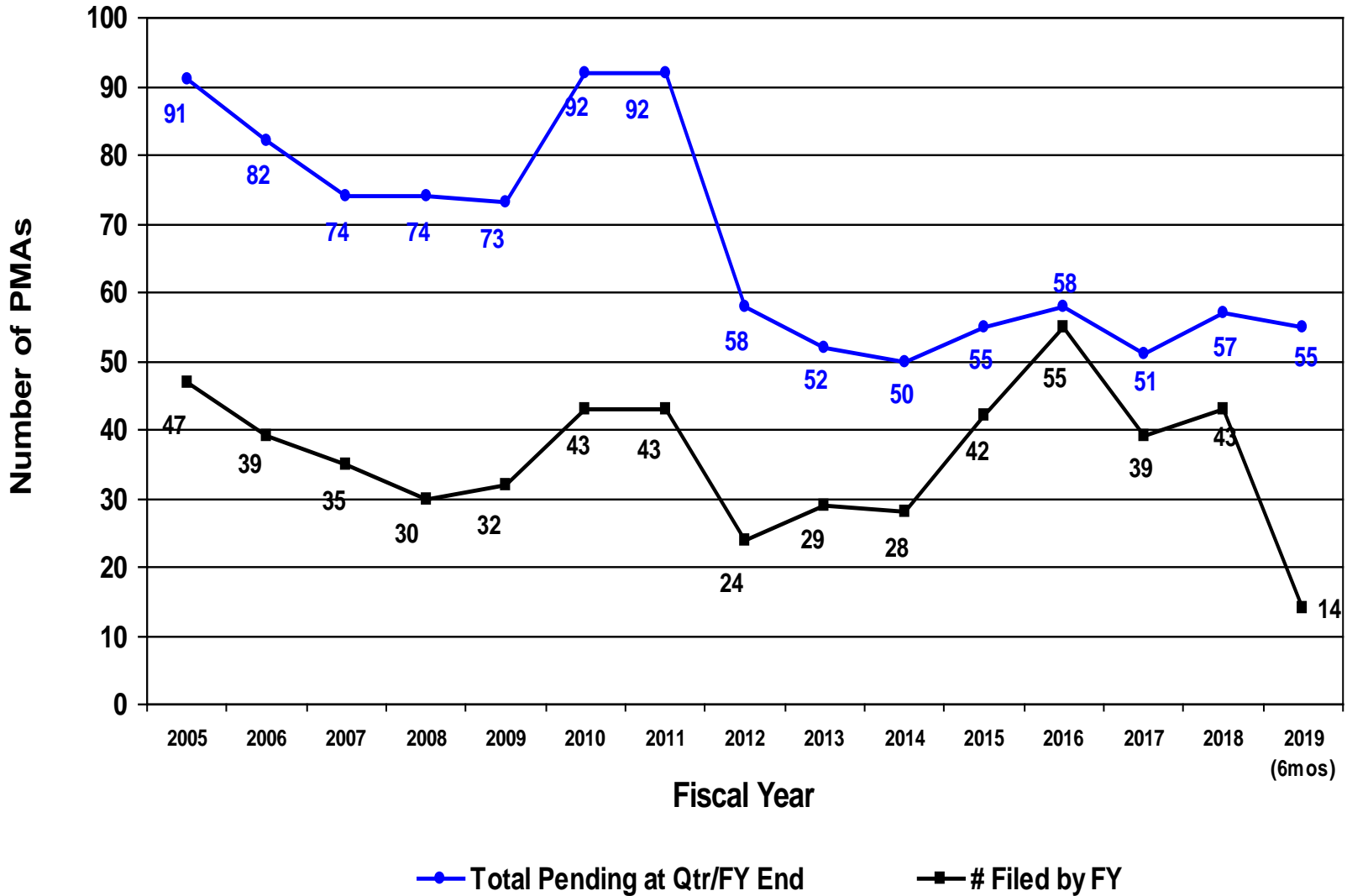


Numbers Filed: 2007 = 31; 2008 = 29; 2009 = 36; 2010 = 50; 2011 = 37; 2012 = 32; 2013 = 27; 2014 = 36; 2015 = 62; 2016 = 70; 2017 = 60; 2018 = 64

◆ Avg FDA Days to MDUFA Decision PMAO-PTS ● Avg MFR Days to MDUFA Decision PMAO-PTS ■ Avg Total Days to MDUFA Decision PMAO-PTS

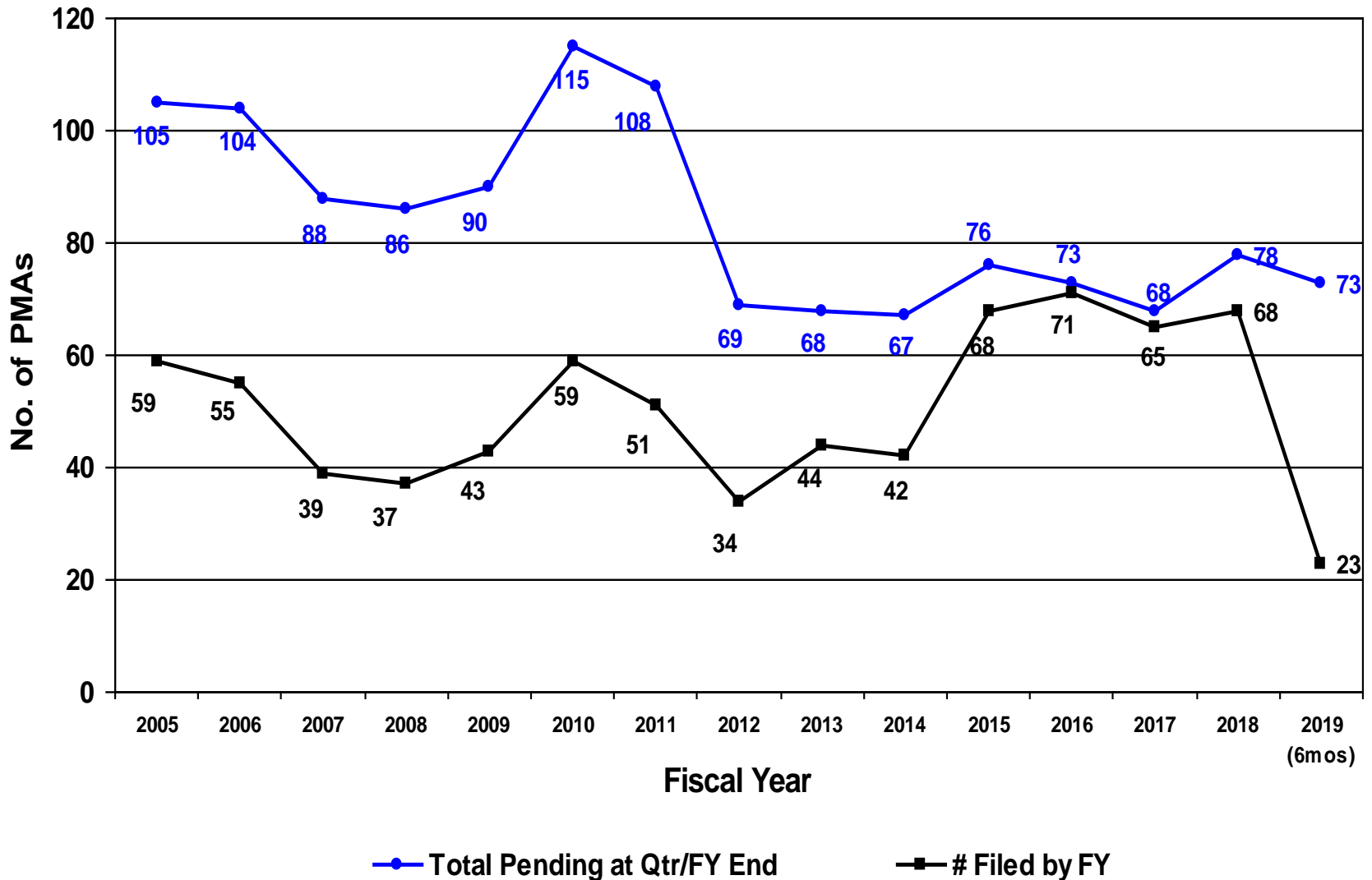
Performance data from FY13 onward map to Table 1.7. Numbers filed map to table 1.5.

## PMA Originals Pending\* at End of Quarter/Year



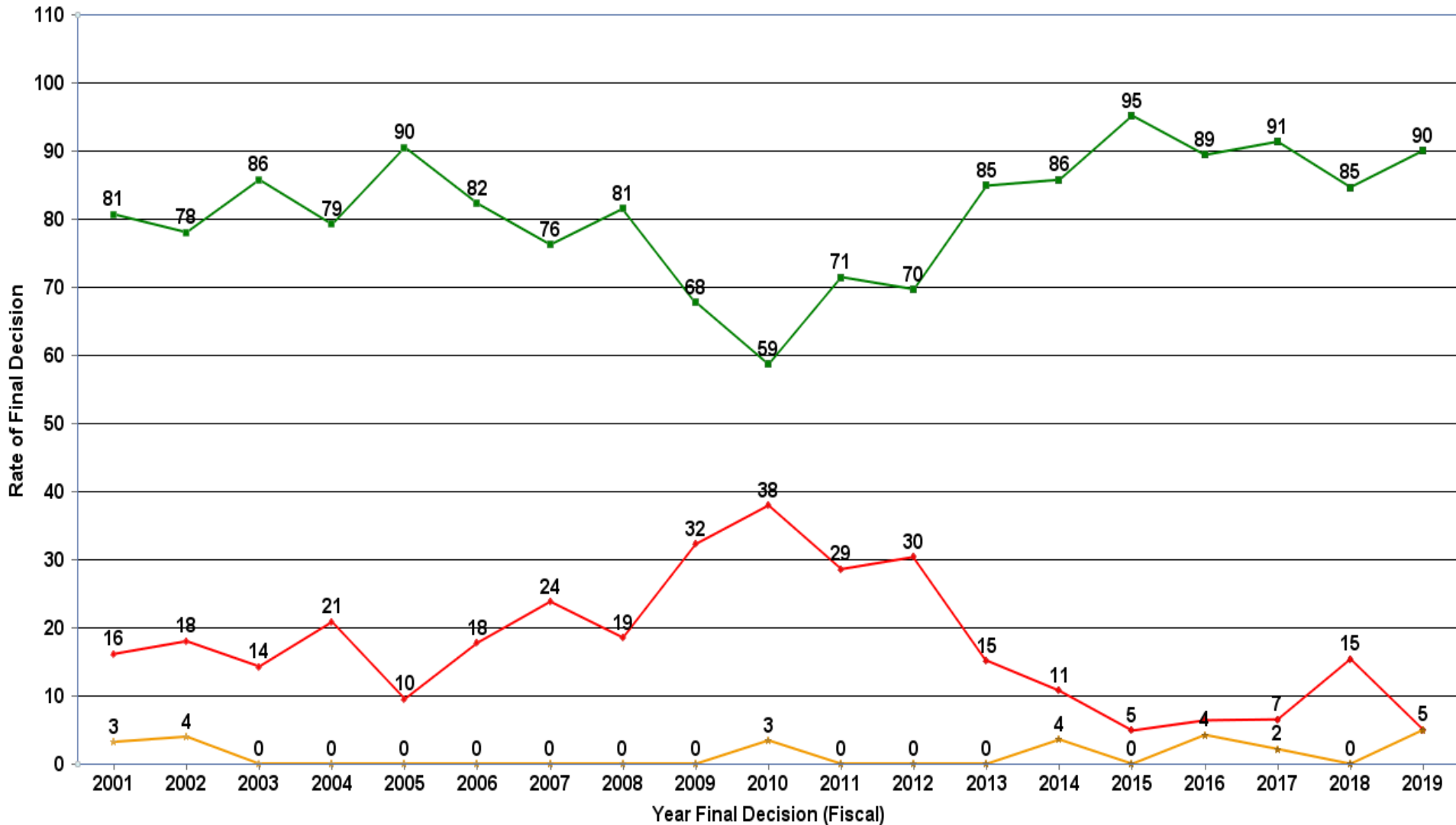
\*Original PMAs under review or on hold. Numbers filed and pending from FY13 onward include only receipts that were accepted for review as of end of quarter/year. 28 of 442

# PMA Originals and Panel Track Supplements Pending\* at End of Quarter/Year



\*Original PMAs/PTS under review or on hold. Numbers filed and pending from FY13 onward include only receipts that were accepted for review as of end of quarter/year. 29 of 442

PMA Originals Rates of Approval, Withdrawal and Other Decisions by FY of Final Decision

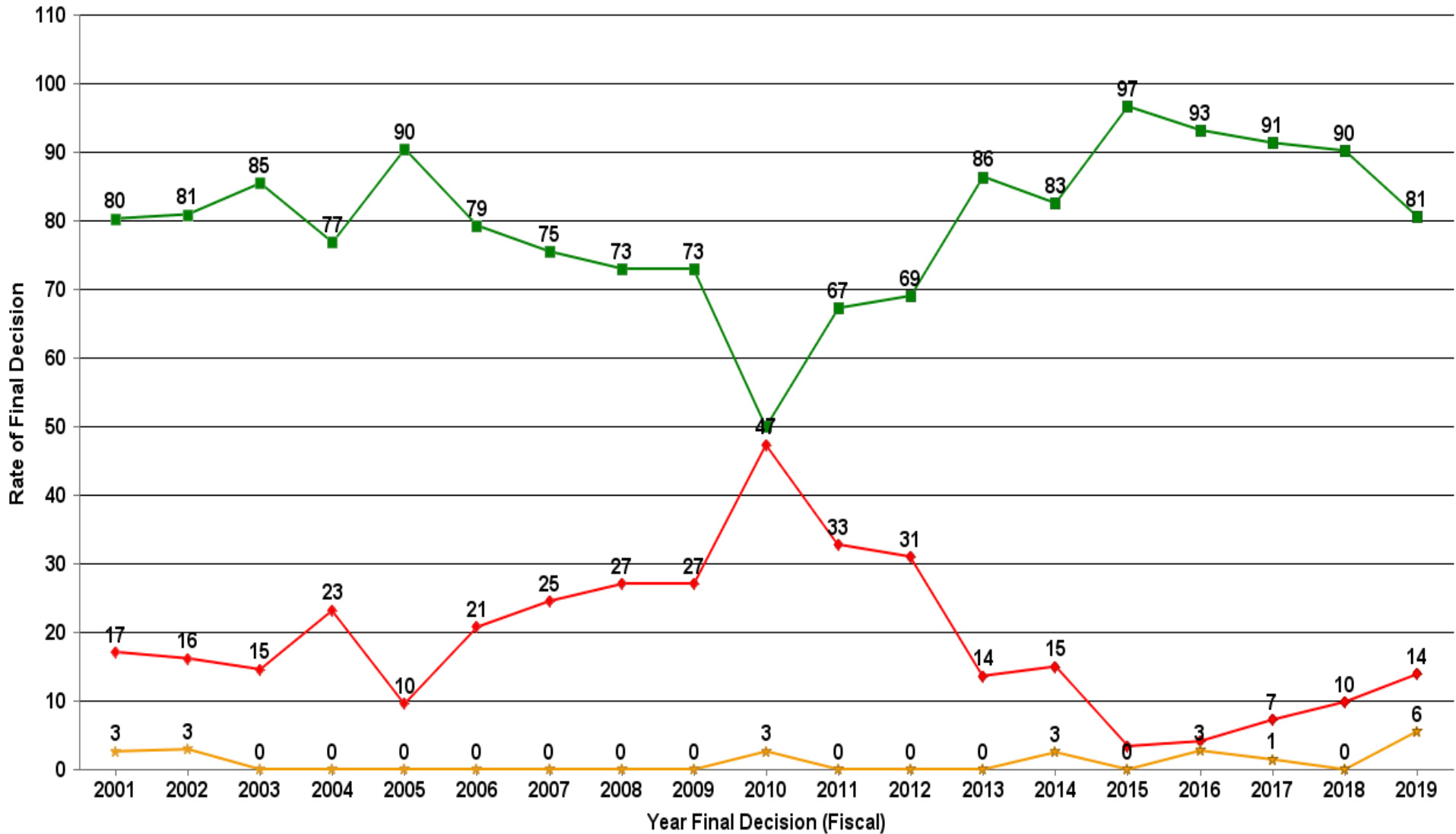


Current FY data represents a partial year in 1st, 2nd and 3rd quarter reporting.

■ % Approved PMAO ♦ % WTDR PMAO ★ % Other PMAO

Submissions deleted due to lack of response were counted as “withdrawals” prior to FY16. Submissions deleted due to lack of response prior to MDUFA decision are counted as “withdrawals” from FY16 onward. Submissions deleted due to lack of response post-MDUFA decision are considered “other” decisions from FY16 onward

PMA Originals and Panel Track Supplements Rates of Approval, Withdrawal and Other Decisions by FY of Final Decision



Current FY data represents a partial year in 1st, 2nd and 3rd quarter reporting.

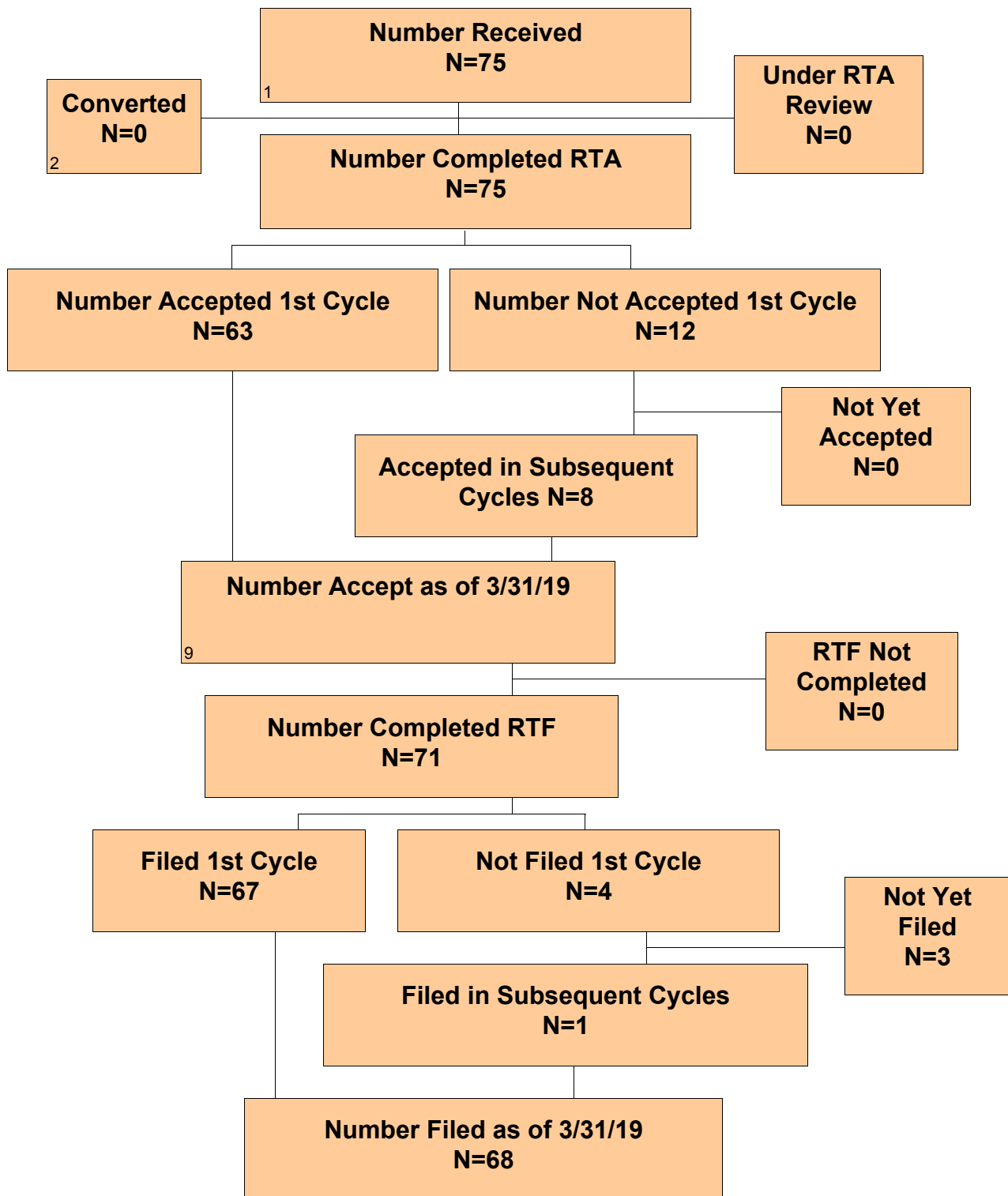
■ % Approved PMAO-PTS ♦ % WTDR PMAO-PTS (Incl DELE Handled As WTDR) ★ % All Other PMAO-PTS

Submissions deleted due to lack of response were counted as “withdrawals” prior to FY16. Submissions deleted due to lack of response prior to MDUFA decision are counted as “withdrawals” from FY16 onward. Submissions deleted due to lack of response post-MDUFA decision are considered “other” decisions from FY16 onward

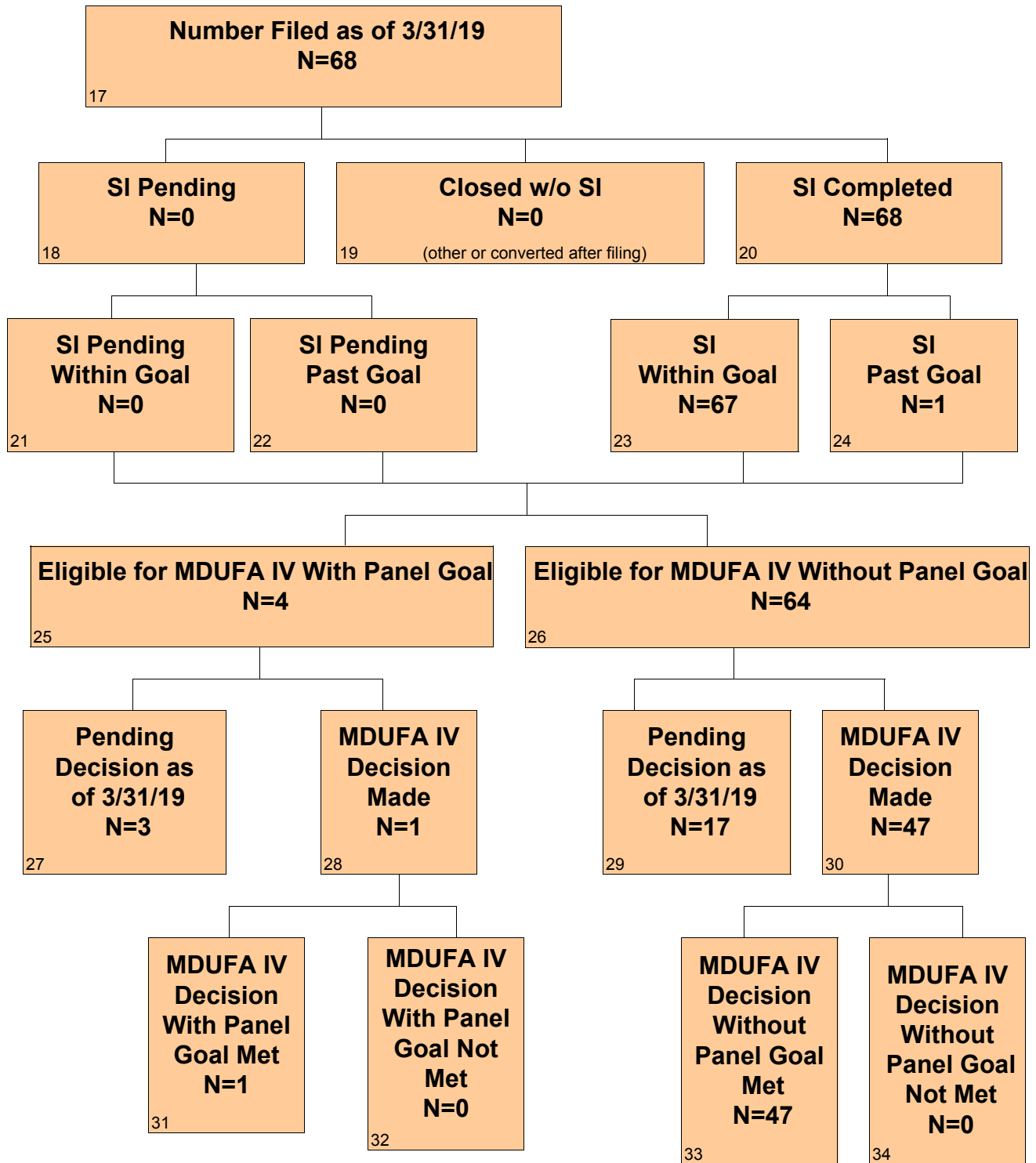
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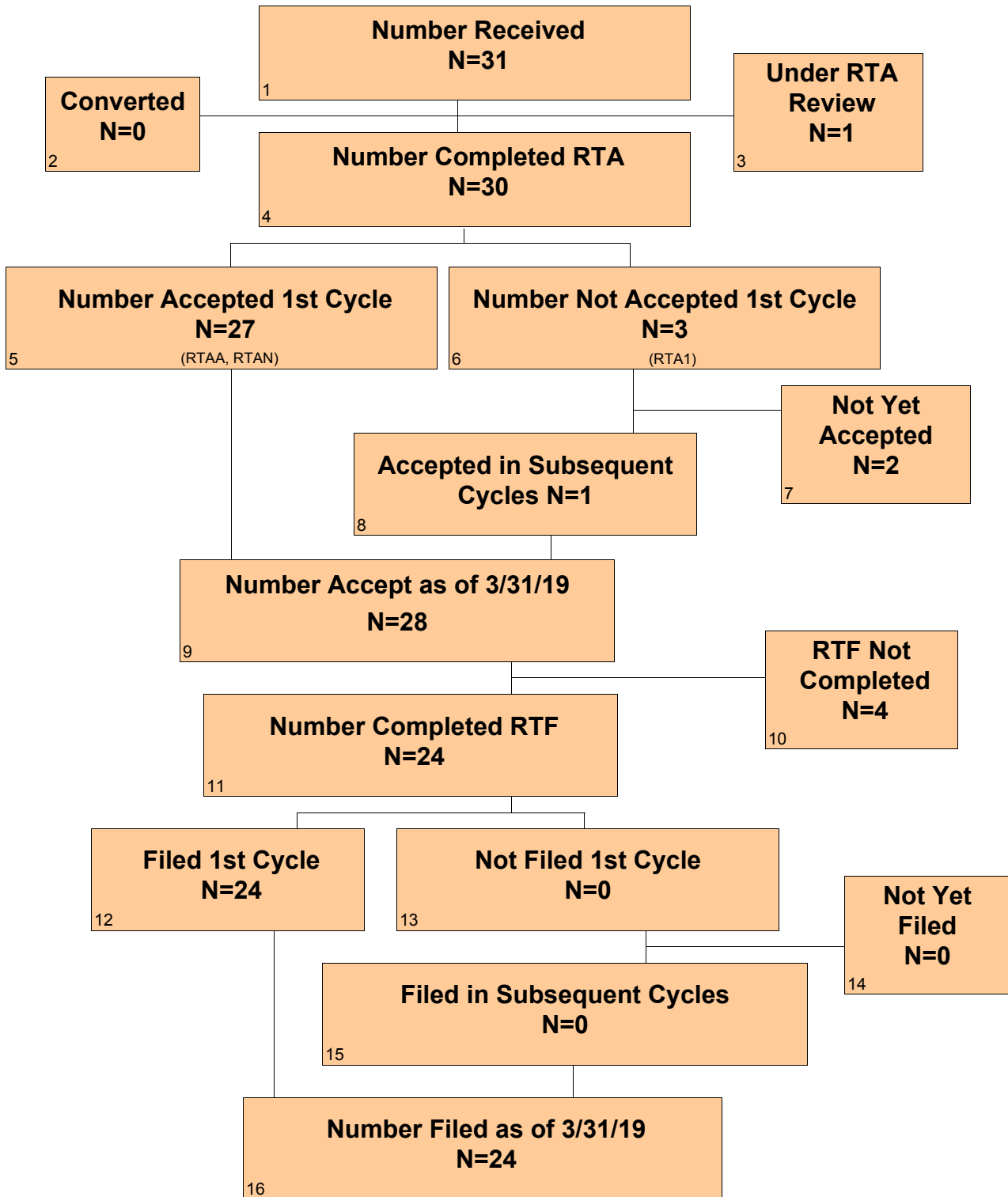
# CDRH PMA Original and Panel Track Supplements - FY 2018 as of 3/31/19



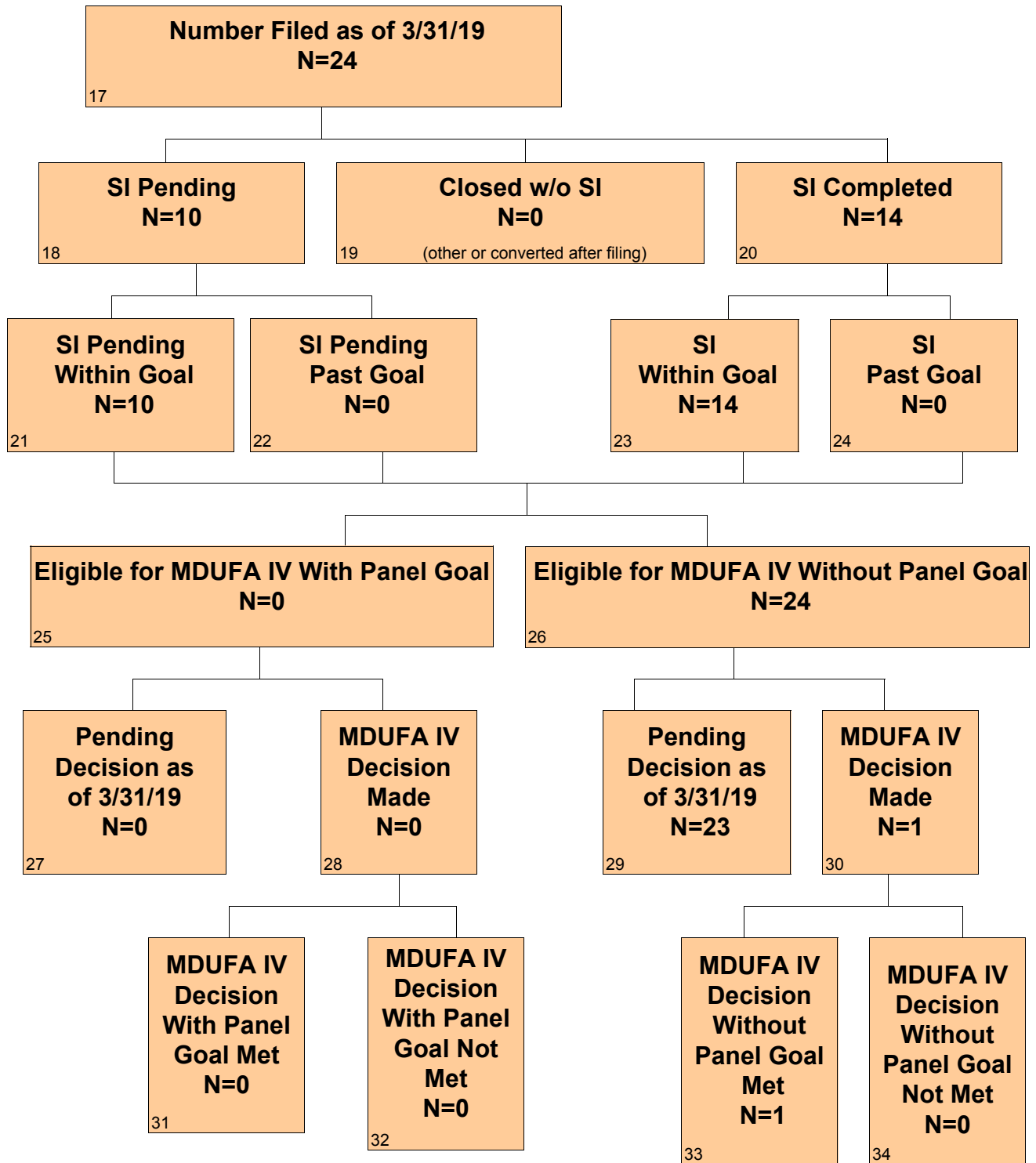
# CDRH PMA Original and Panel Track Supplements - FY 2018 as of 3/31/19 Continued



# CDRH PMA Original and Panel Track Supplements - FY 2019 as of 3/31/19



# CDRH PMA Original and Panel Track Supplements - FY 2019 as of 3/31/19 Continued



## Section 1 PMA Original and Panel-Track Supplements - Center Level Metric

Table 1.1 CDRH - PMA Original and Panel-Track Supplements - Acceptance Review Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	75	31			
Closed Before RTA Action	0	0			
Number with Accepted RTA Review	62	26			
Number Without a RTA Review and > 15 Days Since Date Received	1	1			
Number Without a RTA Review and <= 15 Days Since Date Received	0	1			
Number Not Accepted for Filing Review	12	3			
Rate of Submissions Not Accepted for Filing Review	16.00%	10.00%			

Table 1.2 CDRH - PMA Original and Panel-Track Supplements - Filing Review Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	75	31			
Number Accepted	63	27			
Completed RTF	71	24			
Number Not Filed	4	0			
Rate of Submissions Not Filed	5.63%	0%			

Table 1.3 CDRH - PMA Original and Panel-Track Supplements Substantive Interaction

### Performance Goal

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	68	24			
SI Goal Met	67	14			
SI Goal Not Met	1	0			
SI Pending Within Goal	0	10			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	98.53%	100%			

**Table 1.4 CDRH - PMA Original and Panel-Track Supplements Substantive Interaction Metric - Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number of Substantive Interactions	68	14			
Average Number of FDA Days to Substantive Interaction	86.76	85.86			
20th Percentile FDA Days to Substantive Interaction	84	87			
40th Percentile FDA Days to Substantive Interaction	88	88			
60th Percentile FDA Days to Substantive Interaction	90	89			
80th Percentile FDA Days to Substantive Interaction	90	90			
Maximum FDA Days to Substantive Interaction	178	90			

**Table 1.5 CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>
Number of PMAs Filed	64	24			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	47	1			
MDUFA IV Decision Goal Met	47	1			
PMAs Pending MDUFA IV Decision	17	23			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

**Table 1.6 CDRH - PMA Original and Panel-Track Supplements (with Panel Review) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>
Number of PMAs Filed	4	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	1	0			
MDUFA IV Decision Goal Met	1	0			
PMAs Pending MDUFA IV Decision	3	0			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	N/A			

**Table 1.7 CDRH - PMA Original and Panel-Track Supplements (Without Panel Review)  
Performance Metric - Time to MDUFA IV Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number with MDUFA IV Decision	47	1			
<b>Average FDA Days to MDUFA IV Decision</b>	152.62	128.00			
20th Percentile FDA Days to MDUFA IV Decision	113	128			
40th Percentile FDA Days to MDUFA IV Decision	170	128			
60th Percentile FDA Days to MDUFA IV Decision	178	128			
80th Percentile FDA Days to MDUFA IV Decision	180	128			
Maximum FDA Days to MDUFA IV Decision	180	128			
<b>Average Industry Days to MDUFA IV Decision</b>	56.21	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	46	0			
80th Percentile Industry Days to MDUFA IV Decision	117	0			
Maximum Industry Days to MDUFA IV Decision	283	0			
<b>Average Total Days to MDUFA IV Decision</b>	208.83	128.00			
20th Percentile Total Days to MDUFA IV Decision	148	128			
40th Percentile Total Days to MDUFA IV Decision	178	128			
60th Percentile Total Days to MDUFA IV Decision	202	128			
80th Percentile Total Days to MDUFA IV Decision	264	128			
Maximum Total Days to MDUFA IV Decision	463	128			

**Table 1.8 CDRH - PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Time to MDUFA IV Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number with MDUFA IV Decision	1	0			
<b>Average FDA Days to MDUFA IV Decision</b>	197.00	0.00			
20th Percentile FDA Days to MDUFA IV Decision	197	0			
40th Percentile FDA Days to MDUFA IV Decision	197	0			
60th Percentile FDA Days to MDUFA IV Decision	197	0			
80th Percentile FDA Days to MDUFA IV Decision	197	0			
Maximum FDA Days to MDUFA IV Decision	197	0			
<b>Average Industry Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	0	0			
80th Percentile Industry Days to MDUFA IV Decision	0	0			
Maximum Industry Days to MDUFA IV Decision	0	0			
<b>Average Total Days to MDUFA IV Decision</b>	197.00	0.00			
20th Percentile Total Days to MDUFA IV Decision	197	0			
40th Percentile Total Days to MDUFA IV Decision	197	0			
60th Percentile Total Days to MDUFA IV Decision	197	0			
80th Percentile Total Days to MDUFA IV Decision	197	0			
Maximum Total Days to MDUFA IV Decision	197	0			



**Table 1.9 CDRH - PMA Original and Panel-Track Supplements (Without Panel Review)**

**Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	64	24			
Number with MDUFA IV Decision	47	1			
Number of Withdrawal	6	0			
Number of Not Approvable	5	0			
Number of Deleted	0	0			
Rate of Withdrawal	12.77%	0%			
Rate of Not Approvable	10.64%	0%			

**Table 1.10 CDRH - PMA Original and Panel-Track Supplements (with Panel Review)**

**Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	4	0			
Number With MDUFA IV Decision	1	0			
Number of Withdrawal	0	0			
Number of Not Approvable	0	0			
Number of Deleted	0	0			
Rate of Withdrawal	0%	N/A			
Rate of Not Approvable	0%	N/A			

**Table 1.11 CDRH - PMA Original and Panel-Track Supplements (Without Panel Review)**

**Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 1.12 CDRH - PMA Original and Panel-Track Supplements (with Panel Review)**

**Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 1.13 CDRH - LDT PMA Original and Panel-Track Supplements Metric\***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days
Number of PMAs Filed	1	2			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	1	0			
MDUFA IV Decision Goal Met	1	0			
PMAs Pending MDUFA IV Decision	0	2			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	N/A			

\*Includes submission that went to panel

**Table 1.14 CDRH - Conventional IVD (Non-LDT) PMA Original and Panel-Track Supplements Metric\***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days
Number of PMAs Filed	15	10			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	12	0			
MDUFA IV Decision Goal Met	12	0			
PMAs Pending MDUFA IV Decision	3	10			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	N/A			

\*Includes submission that went to panel

## Section 1 PMA Original and Panel-Track Supplements - Office Level Metric

**Table 1.1 ODE - CDRH - PMA Original and Panel-Track Supplements - Acceptance Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	58	18			
Closed Before RTA Action	0	0			
Number with Accepted RTA review	45	14			
Number Without a RTA Review and > 15 Days Since Date Received	1	1			
Number Without a RTA Review and <= 15 Days Since Date Received	0	1			
Number Not Accepted for Filing Review	12	2			
Rate of Submissions Not Accepted for Filing Review	20.69%	11.76%			

**Table 1.2 ODE - CDRH - PMA Original and Panel-Track Supplements - Filing Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	58	18			
Number Accepted	46	15			
Completed RTF	54	12			
Number Not Filed	4	0			
Rate of Submissions Not Filed	7.41%	0%			

**Table 1.3 ODE - CDRH - PMA Original and Panel-Track Supplements Substantive Interaction Performance Goal**

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	51	12			
SI Goal Met	50	7			
SI Goal Not Met	1	0			
SI Pending Within Goal	0	5			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	98.04%	100%			

**Table 1.4 ODE - CDRH - PMA Original and Panel-Track Supplements Substantive Interaction Metric - Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number of Substantive Interactions	51	7			
Average Number of FDA Days to Substantive Interaction	87.59	83.00			
20th Percentile FDA Days to Substantive Interaction	86	74			
40th Percentile FDA Days to Substantive Interaction	88	87			
60th Percentile FDA Days to Substantive Interaction	90	89			
80th Percentile FDA Days to Substantive Interaction	90	90			
Maximum FDA Days to Substantive Interaction	178	90			

**Table 1.5 ODE - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>
Number of PMAs Filed	47	12			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	33	1			
MDUFA IV Decision Goal Met	33	1			
PMAs Pending MDUFA IV Decision	14	11			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

**Table 1.6 ODE - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>
Number of PMAs Filed	4	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	1	0			
MDUFA IV Decision Goal Met	1	0			
PMAs Pending MDUFA IV Decision	3	0			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	N/A			

**Table 1.7 ODE - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review)  
Performance Metric - Time to MDUFA IV Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number with MDUFA IV Decision	33	1			
<b>Average FDA Days to MDUFA IV Decision</b>	169.70	128.00			
20th Percentile FDA Days to MDUFA IV Decision	170	128			
40th Percentile FDA Days to MDUFA IV Decision	178	128			
60th Percentile FDA Days to MDUFA IV Decision	179	128			
80th Percentile FDA Days to MDUFA IV Decision	180	128			
Maximum FDA Days to MDUFA IV Decision	180	128			
<b>Average Industry Days to MDUFA IV Decision</b>	57.42	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	45	0			
80th Percentile Industry Days to MDUFA IV Decision	140	0			
Maximum Industry Days to MDUFA IV Decision	283	0			
<b>Average Total Days to MDUFA IV Decision</b>	227.12	128.00			
20th Percentile Total Days to MDUFA IV Decision	177	128			
40th Percentile Total Days to MDUFA IV Decision	180	128			
60th Percentile Total Days to MDUFA IV Decision	224	128			
80th Percentile Total Days to MDUFA IV Decision	288	128			
Maximum Total Days to MDUFA IV Decision	463	128			

**Table 1.8 ODE - CDRH - PMA Original and Panel-Track Supplements (with Panel Review)  
Performance Metric - Time to MDUFA IV Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number with MDUFA IV Decision	1	0			
<b>Average FDA Days to MDUFA IV Decision</b>	197.00	0.00			
20th Percentile FDA Days to MDUFA IV Decision	197	0			
40th Percentile FDA Days to MDUFA IV Decision	197	0			
60th Percentile FDA Days to MDUFA IV Decision	197	0			
80th Percentile FDA Days to MDUFA IV Decision	197	0			
Maximum FDA Days to MDUFA IV Decision	197	0			
<b>Average Industry Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	0	0			
80th Percentile Industry Days to MDUFA IV Decision	0	0			
Maximum Industry Days to MDUFA IV Decision	0	0			
<b>Average Total Days to MDUFA IV Decision</b>	197.00	0.00			
20th Percentile Total Days to MDUFA IV Decision	197	0			
40th Percentile Total Days to MDUFA IV Decision	197	0			
60th Percentile Total Days to MDUFA IV Decision	197	0			
80th Percentile Total Days to MDUFA IV Decision	197	0			
Maximum Total Days to MDUFA IV Decision	197	0			

**Table 1.9 ODE - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review)  
Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	47	12			
Number with MDUFA IV Decision	33	1			
Number of Withdrawal	1	0			
Number of Not Approvable	4	0			
Number of Deleted	0	0			
Rate of Withdrawal	3.03%	0%			
Rate of Not Approvable	12.12%	0%			

**Table 1.10 ODE - CDRH - PMA Original and Panel-Track Supplements (with Panel Review)  
Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	4	0			
Number With MDUFA IV Decision	1	0			
Number of Withdrawal	0	0			
Number of Not Approvable	0	0			
Number of Deleted	0	0			
Rate of Withdrawal	0%	N/A			
Rate of Not Approvable	0%	N/A			

**Table 1.11 ODE - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review)  
Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 1.12 ODE - CDRH - PMA Original and Panel-Track Supplements (with Panel Review)  
Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 1.13 ODE - CDRH - LDT PMA Original and Panel-Track Supplements Metric\***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days
Number of PMAs Filed	N/A	N/A			
Non-MDUFA IV Decision	N/A	N/A			
MDUFA IV Decision	N/A	N/A			
MDUFA IV Decision Goal Met	N/A	N/A			
PMAs Pending MDUFA IV Decision	N/A	N/A			
PMAs Pending MDUFA IV Decision Past Goal	N/A	N/A			
Current Performance Percent Goal Met	N/A	N/A			

\*Includes submission that went to panel

**Table 1.14 ODE - CDRH - Conventional IVD (Non-LDT) PMA Original and Panel-Track Supplements Metric\***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days
Number of PMAs Filed	N/A	N/A			
Non-MDUFA IV Decision	N/A	N/A			
MDUFA IV Decision	N/A	N/A			
MDUFA IV Decision Goal Met	N/A	N/A			
PMAs Pending MDUFA IV Decision	N/A	N/A			
PMAs Pending MDUFA IV Decision Past Goal	N/A	N/A			
Current Performance Percent Goal Met	N/A	N/A			

\*Includes submission that went to panel



## Section 1 PMA Original and Panel-Track Supplements - Office Level Metric

**Table 1.1 OIR - CDRH - PMA Original and Panel-Track Supplements - Acceptance Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	17	13			
Closed Before RTA Action	0	0			
Number with Accepted RTA review	17	12			
Number Without a RTA Review and > 15 Days Since Date Received	0	0			
Number Without a RTA Review and <= 15 Days Since Date Received	0	0			
Number Not Accepted for Filing Review	0	1			
Rate of Submissions Not Accepted for Filing Review	0%	7.69%			

**Table 1.2 OIR - CDRH - PMA Original and Panel-Track Supplements - Filing Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	17	13			
Number Accepted	17	12			
Completed RTF	17	12			
Number Not Filed	0	0			
Rate of Submissions Not Filed	0%	0%			

**Table 1.3 OIR - CDRH - PMA Original and Panel-Track Supplements Substantive Interaction Performance Goal**

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	17	12			
SI Goal Met	17	7			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	5			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	100%	100%			

**Table 1.4 OIR - CDRH - PMA Original and Panel-Track Supplements Substantive Interaction Metric - Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number of Substantive Interactions	17	7			
Average Number of FDA Days to Substantive Interaction	84.29	88.71			
20th Percentile FDA Days to Substantive Interaction	84	88			
40th Percentile FDA Days to Substantive Interaction	87	88			
60th Percentile FDA Days to Substantive Interaction	89	89			
80th Percentile FDA Days to Substantive Interaction	90	90			
Maximum FDA Days to Substantive Interaction	90	90			

**Table 1.5 OIR - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>
Number of PMAs Filed	17	12			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	14	0			
MDUFA IV Decision Goal Met	14	0			
PMAs Pending MDUFA IV Decision	3	12			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	N/A			

**Table 1.6 OIR - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>
Number of PMAs Filed	0	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	0	0			
MDUFA IV Decision Goal Met	0	0			
PMAs Pending MDUFA IV Decision	0	0			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	N/A	N/A			

**Table 1.7 OIR - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review)  
Performance Metric - Time to MDUFA IV Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number with MDUFA IV Decision	14	0			
<b>Average FDA Days to MDUFA IV Decision</b>	112.36	0.00			
20th Percentile FDA Days to MDUFA IV Decision	88	0			
40th Percentile FDA Days to MDUFA IV Decision	90	0			
60th Percentile FDA Days to MDUFA IV Decision	114	0			
80th Percentile FDA Days to MDUFA IV Decision	148	0			
Maximum FDA Days to MDUFA IV Decision	180	0			
<b>Average Industry Days to MDUFA IV Decision</b>	53.36	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	48	0			
80th Percentile Industry Days to MDUFA IV Decision	89	0			
Maximum Industry Days to MDUFA IV Decision	268	0			
<b>Average Total Days to MDUFA IV Decision</b>	165.71	0.00			
20th Percentile Total Days to MDUFA IV Decision	90	0			
40th Percentile Total Days to MDUFA IV Decision	119	0			
60th Percentile Total Days to MDUFA IV Decision	167	0			
80th Percentile Total Days to MDUFA IV Decision	234	0			
Maximum Total Days to MDUFA IV Decision	448	0			

**Table 1.8 OIR - CDRH - PMA Original and Panel-Track Supplements (with Panel Review)  
Performance Metric - Time to MDUFA IV Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number with MDUFA IV Decision	0	0			
<b>Average FDA Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile FDA Days to MDUFA IV Decision	0	0			
40th Percentile FDA Days to MDUFA IV Decision	0	0			
60th Percentile FDA Days to MDUFA IV Decision	0	0			
80th Percentile FDA Days to MDUFA IV Decision	0	0			
Maximum FDA Days to MDUFA IV Decision	0	0			
<b>Average Industry Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	0	0			
80th Percentile Industry Days to MDUFA IV Decision	0	0			
Maximum Industry Days to MDUFA IV Decision	0	0			
<b>Average Total Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile Total Days to MDUFA IV Decision	0	0			
40th Percentile Total Days to MDUFA IV Decision	0	0			
60th Percentile Total Days to MDUFA IV Decision	0	0			
80th Percentile Total Days to MDUFA IV Decision	0	0			
Maximum Total Days to MDUFA IV Decision	0	0			

**Table 1.9 OIR - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review)  
Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	17	12			
Number with MDUFA IV Decision	14	0			
Number of Withdrawal	5	0			
Number of Not Approvable	1	0			
Number of Deleted	0	0			
Rate of Withdrawal	35.71%	N/A			
Rate of Not Approvable	7.14%	N/A			

**Table 1.10 OIR - CDRH - PMA Original and Panel-Track Supplements (with Panel Review)  
Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	0	0			
Number With MDUFA IV Decision	0	0			
Number of Withdrawal	0	0			
Number of Not Approvable	0	0			
Number of Deleted	0	0			
Rate of Withdrawal	N/A	N/A			
Rate of Not Approvable	N/A	N/A			

**Table 1.11 OIR - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review)  
Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 1.12 OIR - CDRH - PMA Original and Panel-Track Supplements (with Panel Review)  
Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 1.13 OIR - CDRH - LDT PMA Original and Panel-Track Supplements Metric\***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days
Number of PMAs Filed	1	2			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	1	0			
MDUFA IV Decision Goal Met	1	0			
PMAs Pending MDUFA IV Decision	0	2			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	N/A			

\*Includes submission that went to panel

**Table 1.14 OIR - CDRH - Conventional IVD (Non-LDT) PMA Original and Panel-Track Supplements Metric\***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days
Number of PMAs Filed	15	10			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	12	0			
MDUFA IV Decision Goal Met	12	0			
PMAs Pending MDUFA IV Decision	3	10			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	N/A			

\*Includes submission that went to panel

## Section 1 PMA Original and Panel-Track Supplements - Division Level Metric

**Table 1.1 DAGRID - ODE - CDRH - PMA Original and Panel-Track Supplements - Acceptance Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	3	1			
Closed Before RTA Action	0	0			
Number with Accepted RTA review	3	0			
Number Without a RTA Review and > 15 Days Since Date Received	0	0			
Number Without a RTA Review and <= 15 Days Since Date Received	0	0			
Number Not Accepted for Filing Review	0	1			
Rate of Submissions Not Accepted for Filing Review	0%	100%			

**Table 1.2 DAGRID - ODE - CDRH - PMA Original and Panel-Track Supplements - Filing Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	3	1			
Number Accepted	3	0			
Completed RTF	3	0			
Number Not Filed	0	0			
Rate of Submissions Not Filed	0%	N/A			

**Table 1.3 DAGRID - ODE - CDRH - PMA Original and Panel-Track Supplements Substantive Interaction Performance Goal**

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	3	0			
SI Goal Met	3	0			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	0			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	100%	N/A			

**Table 1.4 DAGRID - ODE - CDRH - PMA Original and Panel-Track Supplements Substantive Interaction Metric - Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number of Substantive Interactions	3	0			
Average Number of FDA Days to Substantive Interaction	86.67	0.00			
20th Percentile FDA Days to Substantive Interaction	84	0			
40th Percentile FDA Days to Substantive Interaction	88	0			
60th Percentile FDA Days to Substantive Interaction	90	0			
80th Percentile FDA Days to Substantive Interaction	90	0			
Maximum FDA Days to Substantive Interaction	90	0			

**Table 1.5 DAGRID - ODE - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>
Number of PMAs Filed	3	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	3	0			
MDUFA IV Decision Goal Met	3	0			
PMAs Pending MDUFA IV Decision	0	0			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	N/A			

**Table 1.6 DAGRID - ODE - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>
Number of PMAs Filed	0	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	0	0			
MDUFA IV Decision Goal Met	0	0			
PMAs Pending MDUFA IV Decision	0	0			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	N/A	N/A			



**Table 1.7 DAGRID - ODE - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Time to MDUFA IV Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number with MDUFA IV Decision	3	0			
<b>Average FDA Days to MDUFA IV Decision</b>	176.67	0.00			
20th Percentile FDA Days to MDUFA IV Decision	174	0			
40th Percentile FDA Days to MDUFA IV Decision	177	0			
60th Percentile FDA Days to MDUFA IV Decision	178	0			
80th Percentile FDA Days to MDUFA IV Decision	179	0			
Maximum FDA Days to MDUFA IV Decision	180	0			
<b>Average Industry Days to MDUFA IV Decision</b>	130.33	0.00			
20th Percentile Industry Days to MDUFA IV Decision	48	0			
40th Percentile Industry Days to MDUFA IV Decision	95	0			
60th Percentile Industry Days to MDUFA IV Decision	150	0			
80th Percentile Industry Days to MDUFA IV Decision	211	0			
Maximum Industry Days to MDUFA IV Decision	272	0			
<b>Average Total Days to MDUFA IV Decision</b>	307.00	0.00			
20th Percentile Total Days to MDUFA IV Decision	226	0			
40th Percentile Total Days to MDUFA IV Decision	275	0			
60th Percentile Total Days to MDUFA IV Decision	328	0			
80th Percentile Total Days to MDUFA IV Decision	386	0			
Maximum Total Days to MDUFA IV Decision	444	0			

**Table 1.8 DAGRID - ODE - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Time to MDUFA IV Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number with MDUFA IV Decision	0	0			
<b>Average FDA Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile FDA Days to MDUFA IV Decision	0	0			
40th Percentile FDA Days to MDUFA IV Decision	0	0			
60th Percentile FDA Days to MDUFA IV Decision	0	0			
80th Percentile FDA Days to MDUFA IV Decision	0	0			
Maximum FDA Days to MDUFA IV Decision	0	0			
<b>Average Industry Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	0	0			
80th Percentile Industry Days to MDUFA IV Decision	0	0			
Maximum Industry Days to MDUFA IV Decision	0	0			
<b>Average Total Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile Total Days to MDUFA IV Decision	0	0			
40th Percentile Total Days to MDUFA IV Decision	0	0			
60th Percentile Total Days to MDUFA IV Decision	0	0			
80th Percentile Total Days to MDUFA IV Decision	0	0			
Maximum Total Days to MDUFA IV Decision	0	0			

**Table 1.9 DAGRID - ODE - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	3	0			
Number with MDUFA IV Decision	3	0			
Number of Withdrawal	0	0			
Number of Not Approvable	1	0			
Number of Deleted	0	0			
Rate of Withdrawal	0.00%	N/A			
Rate of Not Approvable	33.33%	N/A			

**Table 1.10 DAGRID - ODE - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	0	0			
Number With MDUFA IV Decision	0	0			
Number of Withdrawal	0	0			
Number of Not Approvable	0	0			
Number of Deleted	0	0			
Rate of Withdrawal	N/A	N/A			
Rate of Not Approvable	N/A	N/A			

**Table 1.11 DAGRID - ODE - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 1.12 DAGRID - ODE - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 1.13 DAGRID - ODE - CDRH - LDT PMA Original and Panel-Track Supplements Metric\***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days
Number of PMAs Filed	N/A	N/A			
Non-MDUFA IV Decision	N/A	N/A			
MDUFA IV Decision	N/A	N/A			
MDUFA IV Decision Goal Met	N/A	N/A			
PMAs Pending MDUFA IV Decision	N/A	N/A			
PMAs Pending MDUFA IV Decision Past Goal	N/A	N/A			
Current Performance Percent Goal Met	N/A	N/A			

\*Includes submission that went to panel

**Table 1.14 DAGRID - ODE - CDRH - Conventional IVD (Non-LDT) PMA Original and Panel-Track Supplements Metric\***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days
Number of PMAs Filed	N/A	N/A			
Non-MDUFA IV Decision	N/A	N/A			
MDUFA IV Decision	N/A	N/A			
MDUFA IV Decision Goal Met	N/A	N/A			
PMAs Pending MDUFA IV Decision	N/A	N/A			
PMAs Pending MDUFA IV Decision Past Goal	N/A	N/A			
Current Performance Percent Goal Met	N/A	N/A			

\*Includes submission that went to panel

## Section 1 PMA Original and Panel-Track Supplements - Division Level Metric

**Table 1.1 DCD - ODE - CDRH - PMA Original and Panel-Track Supplements - Acceptance Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	23	7			
Closed Before RTA Action	0	0			
Number with Accepted RTA review	20	6			
Number Without a RTA Review and > 15 Days Since Date Received	0	0			
Number Without a RTA Review and <= 15 Days Since Date Received	0	1			
Number Not Accepted for Filing Review	3	0			
Rate of Submissions Not Accepted for Filing Review	13.04%	0%			

**Table 1.2 DCD - ODE - CDRH - PMA Original and Panel-Track Supplements - Filing Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	23	7			
Number Accepted	20	6			
Completed RTF	21	4			
Number Not Filed	1	0			
Rate of Submissions Not Filed	4.76%	0%			

**Table 1.3 DCD - ODE - CDRH - PMA Original and Panel-Track Supplements Substantive Interaction Performance Goal**

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	21	4			
SI Goal Met	21	4			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	0			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	100%	100%			

**Table 1.4 DCD - ODE - CDRH - PMA Original and Panel-Track Supplements Substantive Interaction Metric - Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number of Substantive Interactions	21	4			
Average Number of FDA Days to Substantive Interaction	83.05	84.00			
20th Percentile FDA Days to Substantive Interaction	84	81			
40th Percentile FDA Days to Substantive Interaction	87	87			
60th Percentile FDA Days to Substantive Interaction	89	88			
80th Percentile FDA Days to Substantive Interaction	90	89			
Maximum FDA Days to Substantive Interaction	90	90			

**Table 1.5 DCD - ODE - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>
Number of PMAs Filed	20	4			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	17	1			
MDUFA IV Decision Goal Met	17	1			
PMAs Pending MDUFA IV Decision	3	3			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

**Table 1.6 DCD - ODE - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>
Number of PMAs Filed	1	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	1	0			
MDUFA IV Decision Goal Met	1	0			
PMAs Pending MDUFA IV Decision	0	0			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	N/A			

**Table 1.7 DCD - ODE - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Time to MDUFA IV Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number with MDUFA IV Decision	17	1			
<b>Average FDA Days to MDUFA IV Decision</b>	167.88	128.00			
20th Percentile FDA Days to MDUFA IV Decision	162	128			
40th Percentile FDA Days to MDUFA IV Decision	178	128			
60th Percentile FDA Days to MDUFA IV Decision	178	128			
80th Percentile FDA Days to MDUFA IV Decision	180	128			
Maximum FDA Days to MDUFA IV Decision	180	128			
<b>Average Industry Days to MDUFA IV Decision</b>	48.47	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	37	0			
80th Percentile Industry Days to MDUFA IV Decision	139	0			
Maximum Industry Days to MDUFA IV Decision	162	0			
<b>Average Total Days to MDUFA IV Decision</b>	216.35	128.00			
20th Percentile Total Days to MDUFA IV Decision	162	128			
40th Percentile Total Days to MDUFA IV Decision	179	128			
60th Percentile Total Days to MDUFA IV Decision	216	128			
80th Percentile Total Days to MDUFA IV Decision	317	128			
Maximum Total Days to MDUFA IV Decision	340	128			

**Table 1.8 DCD - ODE - CDRH - PMA Original and Panel-Track Supplements (with Panel Review)  
Performance Metric - Time to MDUFA IV Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number with MDUFA IV Decision	1	0			
<b>Average FDA Days to MDUFA IV Decision</b>	197.00	0.00			
20th Percentile FDA Days to MDUFA IV Decision	197	0			
40th Percentile FDA Days to MDUFA IV Decision	197	0			
60th Percentile FDA Days to MDUFA IV Decision	197	0			
80th Percentile FDA Days to MDUFA IV Decision	197	0			
Maximum FDA Days to MDUFA IV Decision	197	0			
<b>Average Industry Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	0	0			
80th Percentile Industry Days to MDUFA IV Decision	0	0			
Maximum Industry Days to MDUFA IV Decision	0	0			
<b>Average Total Days to MDUFA IV Decision</b>	197.00	0.00			
20th Percentile Total Days to MDUFA IV Decision	197	0			
40th Percentile Total Days to MDUFA IV Decision	197	0			
60th Percentile Total Days to MDUFA IV Decision	197	0			
80th Percentile Total Days to MDUFA IV Decision	197	0			
Maximum Total Days to MDUFA IV Decision	197	0			



**Table 1.9 DCD - ODE - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	20	4			
Number with MDUFA IV Decision	17	1			
Number of Withdrawal	0	0			
Number of Not Approvable	1	0			
Number of Deleted	0	0			
Rate of Withdrawal	0%	0%			
Rate of Not Approvable	5.88%	0%			

**Table 1.10 DCD - ODE - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	1	0			
Number With MDUFA IV Decision	1	0			
Number of Withdrawal	0	0			
Number of Not Approvable	0	0			
Number of Deleted	0	0			
Rate of Withdrawal	0%	N/A			
Rate of Not Approvable	0%	N/A			

**Table 1.11 DCD - ODE - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 1.12 DCD - ODE - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 1.13 DCD - ODE - CDRH - LDT PMA Original and Panel-Track Supplements Metric\***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days
Number of PMAs Filed	N/A	N/A			
Non-MDUFA IV Decision	N/A	N/A			
MDUFA IV Decision	N/A	N/A			
MDUFA IV Decision Goal Met	N/A	N/A			
PMAs Pending MDUFA IV Decision	N/A	N/A			
PMAs Pending MDUFA IV Decision Past Goal	N/A	N/A			
Current Performance Percent Goal Met	N/A	N/A			

\*Includes submission that went to panel

**Table 1.14 DCD - ODE - CDRH - Conventional IVD (Non-LDT) PMA Original and Panel-Track Supplements Metric\***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days
Number of PMAs Filed	N/A	N/A			
Non-MDUFA IV Decision	N/A	N/A			
MDUFA IV Decision	N/A	N/A			
MDUFA IV Decision Goal Met	N/A	N/A			
PMAs Pending MDUFA IV Decision	N/A	N/A			
PMAs Pending MDUFA IV Decision Past Goal	N/A	N/A			
Current Performance Percent Goal Met	N/A	N/A			

\*Includes submission that went to panel

## Section 1 PMA Original and Panel-Track Supplements - Division Level Metric

**Table 1.1 DNPMD - ODE - CDRH - PMA Original and Panel-Track Supplements - Acceptance Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	4	3			
Closed Before RTA Action	0	0			
Number with Accepted RTA review	3	2			
Number Without a RTA Review and > 15 Days Since Date Received	0	1			
Number Without a RTA Review and <= 15 Days Since Date Received	0	0			
Number Not Accepted for Filing Review	1	0			
Rate of Submissions Not Accepted for Filing Review	25.00%	0%			

**Table 1.2 DNPMD - ODE - CDRH - PMA Original and Panel-Track Supplements - Filing Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	4	3			
Number Accepted	3	3			
Completed RTF	4	3			
Number Not Filed	0	0			
Rate of Submissions Not Filed	0%	0%			

**Table 1.3 DNPMD - ODE - CDRH - PMA Original and Panel-Track Supplements Substantive Interaction Performance Goal**

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	4	3			
SI Goal Met	3	2			
SI Goal Not Met	1	0			
SI Pending Within Goal	0	1			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	75.00%	100%			

**Table 1.4 DNPMD - ODE - CDRH - PMA Original and Panel-Track Supplements Substantive Interaction Metric - Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number of Substantive Interactions	4	2			
Average Number of FDA Days to Substantive Interaction	90.50	77.50			
20th Percentile FDA Days to Substantive Interaction	90	70			
40th Percentile FDA Days to Substantive Interaction	90	75			
60th Percentile FDA Days to Substantive Interaction	90	80			
80th Percentile FDA Days to Substantive Interaction	91	85			
Maximum FDA Days to Substantive Interaction	92	90			

**Table 1.5 DNPMD - ODE - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>
Number of PMAs Filed	4	3			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	1	0			
MDUFA IV Decision Goal Met	1	0			
PMAs Pending MDUFA IV Decision	3	3			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	N/A			

**Table 1.6 DNPMD - ODE - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>
Number of PMAs Filed	0	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	0	0			
MDUFA IV Decision Goal Met	0	0			
PMAs Pending MDUFA IV Decision	0	0			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	N/A	N/A			

**Table 1.7 DNPMD - ODE - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Time to MDUFA IV Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number with MDUFA IV Decision	1	0			
<b>Average FDA Days to MDUFA IV Decision</b>	180.00	0.00			
20th Percentile FDA Days to MDUFA IV Decision	180	0			
40th Percentile FDA Days to MDUFA IV Decision	180	0			
60th Percentile FDA Days to MDUFA IV Decision	180	0			
80th Percentile FDA Days to MDUFA IV Decision	180	0			
Maximum FDA Days to MDUFA IV Decision	180	0			
<b>Average Industry Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	0	0			
80th Percentile Industry Days to MDUFA IV Decision	0	0			
Maximum Industry Days to MDUFA IV Decision	0	0			
<b>Average Total Days to MDUFA IV Decision</b>	180.00	0.00			
20th Percentile Total Days to MDUFA IV Decision	180	0			
40th Percentile Total Days to MDUFA IV Decision	180	0			
60th Percentile Total Days to MDUFA IV Decision	180	0			
80th Percentile Total Days to MDUFA IV Decision	180	0			
Maximum Total Days to MDUFA IV Decision	180	0			

**Table 1.8 DNPMD - ODE - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Time to MDUFA IV Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number with MDUFA IV Decision	0	0			
<b>Average FDA Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile FDA Days to MDUFA IV Decision	0	0			
40th Percentile FDA Days to MDUFA IV Decision	0	0			
60th Percentile FDA Days to MDUFA IV Decision	0	0			
80th Percentile FDA Days to MDUFA IV Decision	0	0			
Maximum FDA Days to MDUFA IV Decision	0	0			
<b>Average Industry Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	0	0			
80th Percentile Industry Days to MDUFA IV Decision	0	0			
Maximum Industry Days to MDUFA IV Decision	0	0			
<b>Average Total Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile Total Days to MDUFA IV Decision	0	0			
40th Percentile Total Days to MDUFA IV Decision	0	0			
60th Percentile Total Days to MDUFA IV Decision	0	0			
80th Percentile Total Days to MDUFA IV Decision	0	0			
Maximum Total Days to MDUFA IV Decision	0	0			

**Table 1.9 DNPMD - ODE - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	4	3			
Number with MDUFA IV Decision	1	0			
Number of Withdrawal	0	0			
Number of Not Approvable	0	0			
Number of Deleted	0	0			
Rate of Withdrawal	0%	N/A			
Rate of Not Approvable	0%	N/A			

**Table 1.10 DNPMD - ODE - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	0	0			
Number With MDUFA IV Decision	0	0			
Number of Withdrawal	0	0			
Number of Not Approvable	0	0			
Number of Deleted	0	0			
Rate of Withdrawal	N/A	N/A			
Rate of Not Approvable	N/A	N/A			

**Table 1.11 DNPMD - ODE - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 1.12 DNPMD - ODE - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 1.13 DNPMD - ODE - CDRH - LDT PMA Original and Panel-Track Supplements Metric\***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days
Number of PMAs Filed	N/A	N/A			
Non-MDUFA IV Decision	N/A	N/A			
MDUFA IV Decision	N/A	N/A			
MDUFA IV Decision Goal Met	N/A	N/A			
PMAs Pending MDUFA IV Decision	N/A	N/A			
PMAs Pending MDUFA IV Decision Past Goal	N/A	N/A			
Current Performance Percent Goal Met	N/A	N/A			

\*Includes submission that went to panel

**Table 1.14 DNPMD - ODE - CDRH - Conventional IVD (Non-LDT) PMA Original and Panel-Track Supplements Metric\***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days
Number of PMAs Filed	N/A	N/A			
Non-MDUFA IV Decision	N/A	N/A			
MDUFA IV Decision	N/A	N/A			
MDUFA IV Decision Goal Met	N/A	N/A			
PMAs Pending MDUFA IV Decision	N/A	N/A			
PMAs Pending MDUFA IV Decision Past Goal	N/A	N/A			
Current Performance Percent Goal Met	N/A	N/A			

\*Includes submission that went to panel



## Section 1 PMA Original and Panel-Track Supplements - Division Level Metric

Table 1.1 DOD - ODE - CDRH - PMA Original and Panel-Track Supplements - Acceptance

### Review Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	2	2			
Closed Before RTA Action	0	0			
Number with Accepted RTA review	2	1			
Number Without a RTA Review and > 15 Days Since Date Received	0	0			
Number Without a RTA Review and <= 15 Days Since Date Received	0	0			
Number Not Accepted for Filing Review	0	1			
Rate of Submissions Not Accepted for Filing Review	0%	50.00%			

Table 1.2 DOD - ODE - CDRH - PMA Original and Panel-Track Supplements - Filing Review

### Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	2	2			
Number Accepted	2	1			
Completed RTF	2	1			
Number Not Filed	0	0			
Rate of Submissions Not Filed	0%	0%			

Table 1.3 DOD - ODE - CDRH - PMA Original and Panel-Track Supplements Substantive

### Interaction Performance Goal

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	2	1			
SI Goal Met	2	1			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	0			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	100%	100%			

**Table 1.4 DOD - ODE - CDRH - PMA Original and Panel-Track Supplements Substantive Interaction Metric - Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number of Substantive Interactions	2	1			
Average Number of FDA Days to Substantive Interaction	86.50	90.00			
20th Percentile FDA Days to Substantive Interaction	84	90			
40th Percentile FDA Days to Substantive Interaction	86	90			
60th Percentile FDA Days to Substantive Interaction	87	90			
80th Percentile FDA Days to Substantive Interaction	89	90			
Maximum FDA Days to Substantive Interaction	90	90			

**Table 1.5 DOD - ODE - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>
Number of PMAs Filed	2	1			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	2	0			
MDUFA IV Decision Goal Met	2	0			
PMAs Pending MDUFA IV Decision	0	1			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	N/A			

**Table 1.6 DOD - ODE - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>
Number of PMAs Filed	0	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	0	0			
MDUFA IV Decision Goal Met	0	0			
PMAs Pending MDUFA IV Decision	0	0			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	N/A	N/A			

**Table 1.7 DOD - ODE - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Time to MDUFA IV Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number with MDUFA IV Decision	2	0			
<b>Average FDA Days to MDUFA IV Decision</b>	180.00	0.00			
20th Percentile FDA Days to MDUFA IV Decision	180	0			
40th Percentile FDA Days to MDUFA IV Decision	180	0			
60th Percentile FDA Days to MDUFA IV Decision	180	0			
80th Percentile FDA Days to MDUFA IV Decision	180	0			
Maximum FDA Days to MDUFA IV Decision	180	0			
<b>Average Industry Days to MDUFA IV Decision</b>	141.50	0.00			
20th Percentile Industry Days to MDUFA IV Decision	57	0			
40th Percentile Industry Days to MDUFA IV Decision	113	0			
60th Percentile Industry Days to MDUFA IV Decision	170	0			
80th Percentile Industry Days to MDUFA IV Decision	226	0			
Maximum Industry Days to MDUFA IV Decision	283	0			
<b>Average Total Days to MDUFA IV Decision</b>	321.50	0.00			
20th Percentile Total Days to MDUFA IV Decision	237	0			
40th Percentile Total Days to MDUFA IV Decision	293	0			
60th Percentile Total Days to MDUFA IV Decision	350	0			
80th Percentile Total Days to MDUFA IV Decision	406	0			
Maximum Total Days to MDUFA IV Decision	463	0			

**Table 1.8 DOD - ODE - CDRH - PMA Original and Panel-Track Supplements (with Panel Review)  
Performance Metric - Time to MDUFA IV Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number with MDUFA IV Decision	0	0			
<b>Average FDA Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile FDA Days to MDUFA IV Decision	0	0			
40th Percentile FDA Days to MDUFA IV Decision	0	0			
60th Percentile FDA Days to MDUFA IV Decision	0	0			
80th Percentile FDA Days to MDUFA IV Decision	0	0			
Maximum FDA Days to MDUFA IV Decision	0	0			
<b>Average Industry Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	0	0			
80th Percentile Industry Days to MDUFA IV Decision	0	0			
Maximum Industry Days to MDUFA IV Decision	0	0			
<b>Average Total Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile Total Days to MDUFA IV Decision	0	0			
40th Percentile Total Days to MDUFA IV Decision	0	0			
60th Percentile Total Days to MDUFA IV Decision	0	0			
80th Percentile Total Days to MDUFA IV Decision	0	0			
Maximum Total Days to MDUFA IV Decision	0	0			

**Table 1.9 DOD - ODE - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	2	1			
Number with MDUFA IV Decision	2	0			
Number of Withdrawal	0	0			
Number of Not Approvable	0	0			
Number of Deleted	0	0			
Rate of Withdrawal	0%	N/A			
Rate of Not Approvable	0%	N/A			

**Table 1.10 DOD - ODE - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	0	0			
Number With MDUFA IV Decision	0	0			
Number of Withdrawal	0	0			
Number of Not Approvable	0	0			
Number of Deleted	0	0			
Rate of Withdrawal	N/A	N/A			
Rate of Not Approvable	N/A	N/A			

**Table 1.11 DOD - ODE - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 1.12 DOD - ODE - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 1.13 DOD - ODE - CDRH - LDT PMA Original and Panel-Track Supplements Metric\***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days
Number of PMAs Filed	N/A	N/A			
Non-MDUFA IV Decision	N/A	N/A			
MDUFA IV Decision	N/A	N/A			
MDUFA IV Decision Goal Met	N/A	N/A			
PMAs Pending MDUFA IV Decision	N/A	N/A			
PMAs Pending MDUFA IV Decision Past Goal	N/A	N/A			
Current Performance Percent Goal Met	N/A	N/A			

\*Includes submission that went to panel

**Table 1.14 DOD - ODE - CDRH - Conventional IVD (Non-LDT) PMA Original and Panel-Track Supplements Metric\***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days
Number of PMAs Filed	N/A	N/A			
Non-MDUFA IV Decision	N/A	N/A			
MDUFA IV Decision	N/A	N/A			
MDUFA IV Decision Goal Met	N/A	N/A			
PMAs Pending MDUFA IV Decision	N/A	N/A			
PMAs Pending MDUFA IV Decision Past Goal	N/A	N/A			
Current Performance Percent Goal Met	N/A	N/A			

\*Includes submission that went to panel

## Section 1 PMA Original and Panel-Track Supplements - Division Level Metric

**Table 1.1 DOED - ODE - CDRH - PMA Original and Panel-Track Supplements - Acceptance Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	13	3			
Closed Before RTA Action	0	0			
Number with Accepted RTA review	8	3			
Number Without a RTA Review and > 15 Days Since Date Received	0	0			
Number Without a RTA Review and <= 15 Days Since Date Received	0	0			
Number Not Accepted for Filing Review	5	0			
Rate of Submissions Not Accepted for Filing Review	38.46%	0%			

**Table 1.2 DOED - ODE - CDRH - PMA Original and Panel-Track Supplements - Filing Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	13	3			
Number Accepted	8	3			
Completed RTF	13	3			
Number Not Filed	1	0			
Rate of Submissions Not Filed	7.69%	0%			

**Table 1.3 DOED - ODE - CDRH - PMA Original and Panel-Track Supplements Substantive Interaction Performance Goal**

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	12	3			
SI Goal Met	12	0			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	3			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	100%	N/A			

**Table 1.4 DOED - ODE - CDRH - PMA Original and Panel-Track Supplements Substantive Interaction Metric - Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number of Substantive Interactions	12	0			
Average Number of FDA Days to Substantive Interaction	87.00	0.00			
20th Percentile FDA Days to Substantive Interaction	86	0			
40th Percentile FDA Days to Substantive Interaction	87	0			
60th Percentile FDA Days to Substantive Interaction	89	0			
80th Percentile FDA Days to Substantive Interaction	90	0			
Maximum FDA Days to Substantive Interaction	90	0			

**Table 1.5 DOED - ODE - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>
Number of PMAs Filed	12	3			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	7	0			
MDUFA IV Decision Goal Met	7	0			
PMAs Pending MDUFA IV Decision	5	3			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	N/A			

**Table 1.6 DOED - ODE - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>
Number of PMAs Filed	0	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	0	0			
MDUFA IV Decision Goal Met	0	0			
PMAs Pending MDUFA IV Decision	0	0			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	N/A	N/A			



**Table 1.7 DOED - ODE - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Time to MDUFA IV Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number with MDUFA IV Decision	7	0			
<b>Average FDA Days to MDUFA IV Decision</b>	178.14	0.00			
20th Percentile FDA Days to MDUFA IV Decision	177	0			
40th Percentile FDA Days to MDUFA IV Decision	177	0			
60th Percentile FDA Days to MDUFA IV Decision	179	0			
80th Percentile FDA Days to MDUFA IV Decision	180	0			
Maximum FDA Days to MDUFA IV Decision	180	0			
<b>Average Industry Days to MDUFA IV Decision</b>	25.86	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	0	0			
80th Percentile Industry Days to MDUFA IV Decision	69	0			
Maximum Industry Days to MDUFA IV Decision	95	0			
<b>Average Total Days to MDUFA IV Decision</b>	204.00	0.00			
20th Percentile Total Days to MDUFA IV Decision	177	0			
40th Percentile Total Days to MDUFA IV Decision	178	0			
60th Percentile Total Days to MDUFA IV Decision	180	0			
80th Percentile Total Days to MDUFA IV Decision	249	0			
Maximum Total Days to MDUFA IV Decision	271	0			

**Table 1.8 DOED - ODE - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Time to MDUFA IV Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number with MDUFA IV Decision	0	0			
<b>Average FDA Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile FDA Days to MDUFA IV Decision	0	0			
40th Percentile FDA Days to MDUFA IV Decision	0	0			
60th Percentile FDA Days to MDUFA IV Decision	0	0			
80th Percentile FDA Days to MDUFA IV Decision	0	0			
Maximum FDA Days to MDUFA IV Decision	0	0			
<b>Average Industry Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	0	0			
80th Percentile Industry Days to MDUFA IV Decision	0	0			
Maximum Industry Days to MDUFA IV Decision	0	0			
<b>Average Total Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile Total Days to MDUFA IV Decision	0	0			
40th Percentile Total Days to MDUFA IV Decision	0	0			
60th Percentile Total Days to MDUFA IV Decision	0	0			
80th Percentile Total Days to MDUFA IV Decision	0	0			
Maximum Total Days to MDUFA IV Decision	0	0			

**Table 1.9 DOED - ODE - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	12	3			
Number with MDUFA IV Decision	7	0			
Number of Withdrawal	0	0			
Number of Not Approvable	1	0			
Number of Deleted	0	0			
Rate of Withdrawal	0%	N/A			
Rate of Not Approvable	14.29%	N/A			

**Table 1.10 DOED - ODE - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	0	0			
Number With MDUFA IV Decision	0	0			
Number of Withdrawal	0	0			
Number of Not Approvable	0	0			
Number of Deleted	0	0			
Rate of Withdrawal	N/A	N/A			
Rate of Not Approvable	N/A	N/A			

**Table 1.11 DOED - ODE - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 1.12 DOED - ODE - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 1.13 DOED - ODE - CDRH - LDT PMA Original and Panel-Track Supplements Metric\***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days
Number of PMAs Filed	N/A	N/A			
Non-MDUFA IV Decision	N/A	N/A			
MDUFA IV Decision	N/A	N/A			
MDUFA IV Decision Goal Met	N/A	N/A			
PMAs Pending MDUFA IV Decision	N/A	N/A			
PMAs Pending MDUFA IV Decision Past Goal	N/A	N/A			
Current Performance Percent Goal Met	N/A	N/A			

\*Includes submission that went to panel

**Table 1.14 DOED - ODE - CDRH - Conventional IVD (Non-LDT) PMA Original and Panel-Track Supplements Metric\***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days
Number of PMAs Filed	N/A	N/A			
Non-MDUFA IV Decision	N/A	N/A			
MDUFA IV Decision	N/A	N/A			
MDUFA IV Decision Goal Met	N/A	N/A			
PMAs Pending MDUFA IV Decision	N/A	N/A			
PMAs Pending MDUFA IV Decision Past Goal	N/A	N/A			
Current Performance Percent Goal Met	N/A	N/A			

\*Includes submission that went to panel

## Section 1 PMA Original and Panel-Track Supplements - Division Level Metric

**Table 1.1 DRGUD - ODE - CDRH - PMA Original and Panel-Track Supplements - Acceptance Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	10	2			
Closed Before RTA Action	0	0			
Number with Accepted RTA review	8	2			
Number Without a RTA Review and > 15 Days Since Date Received	1	0			
Number Without a RTA Review and <= 15 Days Since Date Received	0	0			
Number Not Accepted for Filing Review	1	0			
Rate of Submissions Not Accepted for Filing Review	10.00%	0%			

**Table 1.2 DRGUD - ODE - CDRH - PMA Original and Panel-Track Supplements - Filing Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	10	2			
Number Accepted	9	2			
Completed RTF	10	1			
Number Not Filed	2	0			
Rate of Submissions Not Filed	20.00%	0%			

**Table 1.3 DRGUD - ODE - CDRH - PMA Original and Panel-Track Supplements Substantive Interaction Performance Goal**

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	8	1			
SI Goal Met	8	0			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	1			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	100%	N/A			

**Table 1.4 DRGUD - ODE - CDRH - PMA Original and Panel-Track Supplements Substantive Interaction Metric - Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number of Substantive Interactions	8	0			
Average Number of FDA Days to Substantive Interaction	99.50	0.00			
20th Percentile FDA Days to Substantive Interaction	87	0			
40th Percentile FDA Days to Substantive Interaction	88	0			
60th Percentile FDA Days to Substantive Interaction	90	0			
80th Percentile FDA Days to Substantive Interaction	91	0			
Maximum FDA Days to Substantive Interaction	178	0			

**Table 1.5 DRGUD - ODE - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>
Number of PMAs Filed	5	1			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	2	0			
MDUFA IV Decision Goal Met	2	0			
PMAs Pending MDUFA IV Decision	3	1			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	N/A			

**Table 1.6 DRGUD - ODE - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>
Number of PMAs Filed	3	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	0	0			
MDUFA IV Decision Goal Met	0	0			
PMAs Pending MDUFA IV Decision	3	0			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	N/A	N/A			

**Table 1.7 DRGUD - ODE - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Time to MDUFA IV Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number with MDUFA IV Decision	2	0			
<b>Average FDA Days to MDUFA IV Decision</b>	135.00	0.00			
20th Percentile FDA Days to MDUFA IV Decision	108	0			
40th Percentile FDA Days to MDUFA IV Decision	126	0			
60th Percentile FDA Days to MDUFA IV Decision	144	0			
80th Percentile FDA Days to MDUFA IV Decision	162	0			
Maximum FDA Days to MDUFA IV Decision	180	0			
<b>Average Industry Days to MDUFA IV Decision</b>	105.00	0.00			
20th Percentile Industry Days to MDUFA IV Decision	70	0			
40th Percentile Industry Days to MDUFA IV Decision	93	0			
60th Percentile Industry Days to MDUFA IV Decision	117	0			
80th Percentile Industry Days to MDUFA IV Decision	140	0			
Maximum Industry Days to MDUFA IV Decision	163	0			
<b>Average Total Days to MDUFA IV Decision</b>	240.00	0.00			
20th Percentile Total Days to MDUFA IV Decision	232	0			
40th Percentile Total Days to MDUFA IV Decision	237	0			
60th Percentile Total Days to MDUFA IV Decision	243	0			
80th Percentile Total Days to MDUFA IV Decision	248	0			
Maximum Total Days to MDUFA IV Decision	253	0			

**Table 1.8 DRGUD - ODE - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Time to MDUFA IV Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number with MDUFA IV Decision	0	0			
<b>Average FDA Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile FDA Days to MDUFA IV Decision	0	0			
40th Percentile FDA Days to MDUFA IV Decision	0	0			
60th Percentile FDA Days to MDUFA IV Decision	0	0			
80th Percentile FDA Days to MDUFA IV Decision	0	0			
Maximum FDA Days to MDUFA IV Decision	0	0			
<b>Average Industry Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	0	0			
80th Percentile Industry Days to MDUFA IV Decision	0	0			
Maximum Industry Days to MDUFA IV Decision	0	0			
<b>Average Total Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile Total Days to MDUFA IV Decision	0	0			
40th Percentile Total Days to MDUFA IV Decision	0	0			
60th Percentile Total Days to MDUFA IV Decision	0	0			
80th Percentile Total Days to MDUFA IV Decision	0	0			
Maximum Total Days to MDUFA IV Decision	0	0			



**Table 1.9 DRGUD - ODE - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	5	1			
Number with MDUFA IV Decision	2	0			
Number of Withdrawal	1	0			
Number of Not Approvable	0	0			
Number of Deleted	0	0			
Rate of Withdrawal	50.00%	N/A			
Rate of Not Approvable	0%	N/A			

**Table 1.10 DRGUD - ODE - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	3	0			
Number With MDUFA IV Decision	0	0			
Number of Withdrawal	0	0			
Number of Not Approvable	0	0			
Number of Deleted	0	0			
Rate of Withdrawal	N/A	N/A			
Rate of Not Approvable	N/A	N/A			

**Table 1.11 DRGUD - ODE - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 1.12 DRGUD - ODE - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 1.13 DRGUD - ODE - CDRH - LDT PMA Original and Panel-Track Supplements Metric\***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days
Number of PMAs Filed	N/A	N/A			
Non-MDUFA IV Decision	N/A	N/A			
MDUFA IV Decision	N/A	N/A			
MDUFA IV Decision Goal Met	N/A	N/A			
PMAs Pending MDUFA IV Decision	N/A	N/A			
PMAs Pending MDUFA IV Decision Past Goal	N/A	N/A			
Current Performance Percent Goal Met	N/A	N/A			

\*Includes submission that went to panel

**Table 1.14 DRGUD - ODE - CDRH - Conventional IVD (Non-LDT) PMA Original and Panel-Track Supplements Metric\***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days
Number of PMAs Filed	N/A	N/A			
Non-MDUFA IV Decision	N/A	N/A			
MDUFA IV Decision	N/A	N/A			
MDUFA IV Decision Goal Met	N/A	N/A			
PMAs Pending MDUFA IV Decision	N/A	N/A			
PMAs Pending MDUFA IV Decision Past Goal	N/A	N/A			
Current Performance Percent Goal Met	N/A	N/A			

\*Includes submission that went to panel

## Section 1 PMA Original and Panel-Track Supplements - Division Level Metric

**Table 1.1 DSD - ODE - CDRH - PMA Original and Panel-Track Supplements - Acceptance Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	3	0			
Closed Before RTA Action	0	0			
Number with Accepted RTA review	1	0			
Number Without a RTA Review and > 15 Days Since Date Received	0	0			
Number Without a RTA Review and <= 15 Days Since Date Received	0	0			
Number Not Accepted for Filing Review	2	0			
Rate of Submissions Not Accepted for Filing Review	66.67%	N/A			

**Table 1.2 DSD - ODE - CDRH - PMA Original and Panel-Track Supplements - Filing Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	3	0			
Number Accepted	1	0			
Completed RTF	1	0			
Number Not Filed	0	0			
Rate of Submissions Not Filed	0%	N/A			

**Table 1.3 DSD - ODE - CDRH - PMA Original and Panel-Track Supplements Substantive Interaction Performance Goal**

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	1	0			
SI Goal Met	1	0			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	0			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	100%	N/A			

**Table 1.4 DSD - ODE - CDRH - PMA Original and Panel-Track Supplements Substantive Interaction Metric - Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number of Substantive Interactions	1	0			
Average Number of FDA Days to Substantive Interaction	88.00	0.00			
20th Percentile FDA Days to Substantive Interaction	88	0			
40th Percentile FDA Days to Substantive Interaction	88	0			
60th Percentile FDA Days to Substantive Interaction	88	0			
80th Percentile FDA Days to Substantive Interaction	88	0			
Maximum FDA Days to Substantive Interaction	88	0			

**Table 1.5 DSD - ODE - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>
Number of PMAs Filed	1	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	1	0			
MDUFA IV Decision Goal Met	1	0			
PMAs Pending MDUFA IV Decision	0	0			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	N/A			

**Table 1.6 DSD - ODE - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>
Number of PMAs Filed	0	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	0	0			
MDUFA IV Decision Goal Met	0	0			
PMAs Pending MDUFA IV Decision	0	0			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	N/A	N/A			

**Table 1.7 DSD - ODE - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Time to MDUFA IV Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number with MDUFA IV Decision	1	0			
<b>Average FDA Days to MDUFA IV Decision</b>	159.00	0.00			
20th Percentile FDA Days to MDUFA IV Decision	159	0			
40th Percentile FDA Days to MDUFA IV Decision	159	0			
60th Percentile FDA Days to MDUFA IV Decision	159	0			
80th Percentile FDA Days to MDUFA IV Decision	159	0			
Maximum FDA Days to MDUFA IV Decision	159	0			
<b>Average Industry Days to MDUFA IV Decision</b>	6.00	0.00			
20th Percentile Industry Days to MDUFA IV Decision	6	0			
40th Percentile Industry Days to MDUFA IV Decision	6	0			
60th Percentile Industry Days to MDUFA IV Decision	6	0			
80th Percentile Industry Days to MDUFA IV Decision	6	0			
Maximum Industry Days to MDUFA IV Decision	6	0			
<b>Average Total Days to MDUFA IV Decision</b>	165.00	0.00			
20th Percentile Total Days to MDUFA IV Decision	165	0			
40th Percentile Total Days to MDUFA IV Decision	165	0			
60th Percentile Total Days to MDUFA IV Decision	165	0			
80th Percentile Total Days to MDUFA IV Decision	165	0			
Maximum Total Days to MDUFA IV Decision	165	0			

**Table 1.8 DSD - ODE - CDRH - PMA Original and Panel-Track Supplements (with Panel Review)  
Performance Metric - Time to MDUFA IV Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number with MDUFA IV Decision	0	0			
<b>Average FDA Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile FDA Days to MDUFA IV Decision	0	0			
40th Percentile FDA Days to MDUFA IV Decision	0	0			
60th Percentile FDA Days to MDUFA IV Decision	0	0			
80th Percentile FDA Days to MDUFA IV Decision	0	0			
Maximum FDA Days to MDUFA IV Decision	0	0			
<b>Average Industry Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	0	0			
80th Percentile Industry Days to MDUFA IV Decision	0	0			
Maximum Industry Days to MDUFA IV Decision	0	0			
<b>Average Total Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile Total Days to MDUFA IV Decision	0	0			
40th Percentile Total Days to MDUFA IV Decision	0	0			
60th Percentile Total Days to MDUFA IV Decision	0	0			
80th Percentile Total Days to MDUFA IV Decision	0	0			
Maximum Total Days to MDUFA IV Decision	0	0			

**Table 1.9 DSD - ODE - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	1	0			
Number with MDUFA IV Decision	1	0			
Number of Withdrawal	0	0			
Number of Not Approvable	1	0			
Number of Deleted	0	0			
Rate of Withdrawal	0%	N/A			
Rate of Not Approvable	100%	N/A			

**Table 1.10 DSD - ODE - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	0	0			
Number With MDUFA IV Decision	0	0			
Number of Withdrawal	0	0			
Number of Not Approvable	0	0			
Number of Deleted	0	0			
Rate of Withdrawal	N/A	N/A			
Rate of Not Approvable	N/A	N/A			

**Table 1.11 DSD - ODE - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 1.12 DSD - ODE - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 1.13 DSD - ODE - CDRH - LDT PMA Original and Panel-Track Supplements Metric\***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days
Number of PMAs Filed	N/A	N/A			
Non-MDUFA IV Decision	N/A	N/A			
MDUFA IV Decision	N/A	N/A			
MDUFA IV Decision Goal Met	N/A	N/A			
PMAs Pending MDUFA IV Decision	N/A	N/A			
PMAs Pending MDUFA IV Decision Past Goal	N/A	N/A			
Current Performance Percent Goal Met	N/A	N/A			

\*Includes submission that went to panel

**Table 1.14 DSD - ODE - CDRH - Conventional IVD (Non-LDT) PMA Original and Panel-Track Supplements Metric\***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days
Number of PMAs Filed	N/A	N/A			
Non-MDUFA IV Decision	N/A	N/A			
MDUFA IV Decision	N/A	N/A			
MDUFA IV Decision Goal Met	N/A	N/A			
PMAs Pending MDUFA IV Decision	N/A	N/A			
PMAs Pending MDUFA IV Decision Past Goal	N/A	N/A			
Current Performance Percent Goal Met	N/A	N/A			

\*Includes submission that went to panel



## Section 1 PMA Original and Panel-Track Supplements - Division Level Metric

**Table 1.1 DCTD - OIR - CDRH - PMA Original and Panel-Track Supplements - Acceptance Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	5	1			
Closed Before RTA Action	0	0			
Number with Accepted RTA review	5	1			
Number Without a RTA Review and > 15 Days Since Date Received	0	0			
Number Without a RTA Review and <= 15 Days Since Date Received	0	0			
Number Not Accepted for Filing Review	0	0			
Rate of Submissions Not Accepted for Filing Review	0%	0%			

**Table 1.2 DCTD - OIR - CDRH - PMA Original and Panel-Track Supplements - Filing Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	5	1			
Number Accepted	5	1			
Completed RTF	5	1			
Number Not Filed	0	0			
Rate of Submissions Not Filed	0%	0%			

**Table 1.3 DCTD - OIR - CDRH - PMA Original and Panel-Track Supplements Substantive Interaction Performance Goal**

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	5	1			
SI Goal Met	5	1			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	0			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	100%	100%			

**Table 1.4 DCTD - OIR - CDRH - PMA Original and Panel-Track Supplements Substantive Interaction Metric - Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number of Substantive Interactions	5	1			
Average Number of FDA Days to Substantive Interaction	88.20	87.00			
20th Percentile FDA Days to Substantive Interaction	86	87			
40th Percentile FDA Days to Substantive Interaction	89	87			
60th Percentile FDA Days to Substantive Interaction	90	87			
80th Percentile FDA Days to Substantive Interaction	90	87			
Maximum FDA Days to Substantive Interaction	90	87			

**Table 1.5 DCTD - OIR - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>
Number of PMAs Filed	5	1			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	5	0			
MDUFA IV Decision Goal Met	5	0			
PMAs Pending MDUFA IV Decision	0	1			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	N/A			

**Table 1.6 DCTD - OIR - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>
Number of PMAs Filed	0	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	0	0			
MDUFA IV Decision Goal Met	0	0			
PMAs Pending MDUFA IV Decision	0	0			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	N/A	N/A			

**Table 1.7 DCTD - OIR - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Time to MDUFA IV Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number with MDUFA IV Decision	5	0			
<b>Average FDA Days to MDUFA IV Decision</b>	105.00	0.00			
20th Percentile FDA Days to MDUFA IV Decision	89	0			
40th Percentile FDA Days to MDUFA IV Decision	90	0			
60th Percentile FDA Days to MDUFA IV Decision	100	0			
80th Percentile FDA Days to MDUFA IV Decision	121	0			
Maximum FDA Days to MDUFA IV Decision	146	0			
<b>Average Industry Days to MDUFA IV Decision</b>	22.20	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	0	0			
80th Percentile Industry Days to MDUFA IV Decision	22	0			
Maximum Industry Days to MDUFA IV Decision	111	0			
<b>Average Total Days to MDUFA IV Decision</b>	127.20	0.00			
20th Percentile Total Days to MDUFA IV Decision	90	0			
40th Percentile Total Days to MDUFA IV Decision	105	0			
60th Percentile Total Days to MDUFA IV Decision	127	0			
80th Percentile Total Days to MDUFA IV Decision	156	0			
Maximum Total Days to MDUFA IV Decision	195	0			

**Table 1.8 DCTD - OIR - CDRH - PMA Original and Panel-Track Supplements (with Panel Review)  
Performance Metric - Time to MDUFA IV Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number with MDUFA IV Decision	0	0			
<b>Average FDA Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile FDA Days to MDUFA IV Decision	0	0			
40th Percentile FDA Days to MDUFA IV Decision	0	0			
60th Percentile FDA Days to MDUFA IV Decision	0	0			
80th Percentile FDA Days to MDUFA IV Decision	0	0			
Maximum FDA Days to MDUFA IV Decision	0	0			
<b>Average Industry Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	0	0			
80th Percentile Industry Days to MDUFA IV Decision	0	0			
Maximum Industry Days to MDUFA IV Decision	0	0			
<b>Average Total Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile Total Days to MDUFA IV Decision	0	0			
40th Percentile Total Days to MDUFA IV Decision	0	0			
60th Percentile Total Days to MDUFA IV Decision	0	0			
80th Percentile Total Days to MDUFA IV Decision	0	0			
Maximum Total Days to MDUFA IV Decision	0	0			

**Table 1.9 DCTD - OIR - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	5	1			
Number with MDUFA IV Decision	5	0			
Number of Withdrawal	1	0			
Number of Not Approvable	1	0			
Number of Deleted	0	0			
Rate of Withdrawal	20.00%	N/A			
Rate of Not Approvable	20.00%	N/A			

**Table 1.10 DCTD - OIR - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	0	0			
Number With MDUFA IV Decision	0	0			
Number of Withdrawal	0	0			
Number of Not Approvable	0	0			
Number of Deleted	0	0			
Rate of Withdrawal	N/A	N/A			
Rate of Not Approvable	N/A	N/A			

**Table 1.11 DCTD - OIR - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 1.12 DCTD - OIR - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 1.13 DCTD - OIR - CDRH - LDT PMA Original and Panel-Track Supplements Metric\***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days
Number of PMAs Filed	0	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	0	0			
MDUFA IV Decision Goal Met	0	0			
PMAs Pending MDUFA IV Decision	0	0			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	N/A	N/A			

\*Includes submission that went to panel

**Table 1.14 DCTD - OIR - CDRH - Conventional IVD (Non-LDT) PMA Original and Panel-Track Supplements Metric\***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days
Number of PMAs Filed	5	1			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	5	0			
MDUFA IV Decision Goal Met	5	0			
PMAs Pending MDUFA IV Decision	0	1			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	N/A			

\*Includes submission that went to panel

## Section 1 PMA Original and Panel-Track Supplements - Division Level Metric

**Table 1.1 DIHD - OIR - CDRH - PMA Original and Panel-Track Supplements - Acceptance Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	1	0			
Closed Before RTA Action	0	0			
Number with Accepted RTA review	1	0			
Number Without a RTA Review and > 15 Days Since Date Received	0	0			
Number Without a RTA Review and <= 15 Days Since Date Received	0	0			
Number Not Accepted for Filing Review	0	0			
Rate of Submissions Not Accepted for Filing Review	0%	N/A			

**Table 1.2 DIHD - OIR - CDRH - PMA Original and Panel-Track Supplements - Filing Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	1	0			
Number Accepted	1	0			
Completed RTF	1	0			
Number Not Filed	0	0			
Rate of Submissions Not Filed	0%	N/A			

**Table 1.3 DIHD - OIR - CDRH - PMA Original and Panel-Track Supplements Substantive Interaction Performance Goal**

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	1	0			
SI Goal Met	1	0			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	0			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	100%	N/A			

**Table 1.4 DIHD - OIR - CDRH - PMA Original and Panel-Track Supplements Substantive Interaction Metric - Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number of Substantive Interactions	1	0			
Average Number of FDA Days to Substantive Interaction	90.00	0.00			
20th Percentile FDA Days to Substantive Interaction	90	0			
40th Percentile FDA Days to Substantive Interaction	90	0			
60th Percentile FDA Days to Substantive Interaction	90	0			
80th Percentile FDA Days to Substantive Interaction	90	0			
Maximum FDA Days to Substantive Interaction	90	0			

**Table 1.5 DIHD - OIR - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>
Number of PMAs Filed	1	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	1	0			
MDUFA IV Decision Goal Met	1	0			
PMAs Pending MDUFA IV Decision	0	0			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	N/A			

**Table 1.6 DIHD - OIR - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>
Number of PMAs Filed	0	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	0	0			
MDUFA IV Decision Goal Met	0	0			
PMAs Pending MDUFA IV Decision	0	0			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	N/A	N/A			



**Table 1.7 DIHD - OIR - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Time to MDUFA IV Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number with MDUFA IV Decision	1	0			
<b>Average FDA Days to MDUFA IV Decision</b>	180.00	0.00			
20th Percentile FDA Days to MDUFA IV Decision	180	0			
40th Percentile FDA Days to MDUFA IV Decision	180	0			
60th Percentile FDA Days to MDUFA IV Decision	180	0			
80th Percentile FDA Days to MDUFA IV Decision	180	0			
Maximum FDA Days to MDUFA IV Decision	180	0			
<b>Average Industry Days to MDUFA IV Decision</b>	268.00	0.00			
20th Percentile Industry Days to MDUFA IV Decision	268	0			
40th Percentile Industry Days to MDUFA IV Decision	268	0			
60th Percentile Industry Days to MDUFA IV Decision	268	0			
80th Percentile Industry Days to MDUFA IV Decision	268	0			
Maximum Industry Days to MDUFA IV Decision	268	0			
<b>Average Total Days to MDUFA IV Decision</b>	448.00	0.00			
20th Percentile Total Days to MDUFA IV Decision	448	0			
40th Percentile Total Days to MDUFA IV Decision	448	0			
60th Percentile Total Days to MDUFA IV Decision	448	0			
80th Percentile Total Days to MDUFA IV Decision	448	0			
Maximum Total Days to MDUFA IV Decision	448	0			

**Table 1.8 DIHD - OIR - CDRH - PMA Original and Panel-Track Supplements (with Panel Review)  
Performance Metric - Time to MDUFA IV Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number with MDUFA IV Decision	0	0			
<b>Average FDA Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile FDA Days to MDUFA IV Decision	0	0			
40th Percentile FDA Days to MDUFA IV Decision	0	0			
60th Percentile FDA Days to MDUFA IV Decision	0	0			
80th Percentile FDA Days to MDUFA IV Decision	0	0			
Maximum FDA Days to MDUFA IV Decision	0	0			
<b>Average Industry Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	0	0			
80th Percentile Industry Days to MDUFA IV Decision	0	0			
Maximum Industry Days to MDUFA IV Decision	0	0			
<b>Average Total Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile Total Days to MDUFA IV Decision	0	0			
40th Percentile Total Days to MDUFA IV Decision	0	0			
60th Percentile Total Days to MDUFA IV Decision	0	0			
80th Percentile Total Days to MDUFA IV Decision	0	0			
Maximum Total Days to MDUFA IV Decision	0	0			

**Table 1.9 DIHD - OIR - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	1	0			
Number with MDUFA IV Decision	1	0			
Number of Withdrawal	0	0			
Number of Not Approvable	0	0			
Number of Deleted	0	0			
Rate of Withdrawal	0%	N/A			
Rate of Not Approvable	0%	N/A			

**Table 1.10 DIHD - OIR - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	0	0			
Number With MDUFA IV Decision	0	0			
Number of Withdrawal	0	0			
Number of Not Approvable	0	0			
Number of Deleted	0	0			
Rate of Withdrawal	N/A	N/A			
Rate of Not Approvable	N/A	N/A			

**Table 1.11 DIHD - OIR - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 1.12 DIHD - OIR - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 1.13 DIHD - OIR - CDRH - LDT PMA Original and Panel-Track Supplements Metric\***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days
Number of PMAs Filed	0	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	0	0			
MDUFA IV Decision Goal Met	0	0			
PMAs Pending MDUFA IV Decision	0	0			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	N/A	N/A			

\*Includes submission that went to panel

**Table 1.14 DIHD - OIR - CDRH - Conventional IVD (Non-LDT) PMA Original and Panel-Track Supplements Metric\***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days
Number of PMAs Filed	1	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	1	0			
MDUFA IV Decision Goal Met	1	0			
PMAs Pending MDUFA IV Decision	0	0			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	N/A			

\*Includes submission that went to panel

## Section 1 PMA Original and Panel-Track Supplements - Division Level Metric

**Table 1.1 DMD - OIR - CDRH - PMA Original and Panel-Track Supplements - Acceptance Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	2	5			
Closed Before RTA Action	0	0			
Number with Accepted RTA review	2	5			
Number Without a RTA Review and > 15 Days Since Date Received	0	0			
Number Without a RTA Review and <= 15 Days Since Date Received	0	0			
Number Not Accepted for Filing Review	0	0			
Rate of Submissions Not Accepted for Filing Review	0%	0%			

**Table 1.2 DMD - OIR - CDRH - PMA Original and Panel-Track Supplements - Filing Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	2	5			
Number Accepted	2	5			
Completed RTF	2	5			
Number Not Filed	0	0			
Rate of Submissions Not Filed	0%	0%			

**Table 1.3 DMD - OIR - CDRH - PMA Original and Panel-Track Supplements Substantive Interaction Performance Goal**

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	2	5			
SI Goal Met	2	4			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	1			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	100%	100%			

**Table 1.4 DMD - OIR - CDRH - PMA Original and Panel-Track Supplements Substantive Interaction Metric - Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number of Substantive Interactions	2	4			
Average Number of FDA Days to Substantive Interaction	84.00	88.75			
20th Percentile FDA Days to Substantive Interaction	84	88			
40th Percentile FDA Days to Substantive Interaction	84	88			
60th Percentile FDA Days to Substantive Interaction	84	89			
80th Percentile FDA Days to Substantive Interaction	84	89			
Maximum FDA Days to Substantive Interaction	84	90			

**Table 1.5 DMD - OIR - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>
Number of PMAs Filed	2	5			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	0	0			
MDUFA IV Decision Goal Met	0	0			
PMAs Pending MDUFA IV Decision	2	5			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	N/A	N/A			

**Table 1.6 DMD - OIR - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>
Number of PMAs Filed	0	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	0	0			
MDUFA IV Decision Goal Met	0	0			
PMAs Pending MDUFA IV Decision	0	0			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	N/A	N/A			

**Table 1.7 DMD - OIR - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Time to MDUFA IV Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number with MDUFA IV Decision	0	0			
<b>Average FDA Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile FDA Days to MDUFA IV Decision	0	0			
40th Percentile FDA Days to MDUFA IV Decision	0	0			
60th Percentile FDA Days to MDUFA IV Decision	0	0			
80th Percentile FDA Days to MDUFA IV Decision	0	0			
Maximum FDA Days to MDUFA IV Decision	0	0			
<b>Average Industry Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	0	0			
80th Percentile Industry Days to MDUFA IV Decision	0	0			
Maximum Industry Days to MDUFA IV Decision	0	0			
<b>Average Total Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile Total Days to MDUFA IV Decision	0	0			
40th Percentile Total Days to MDUFA IV Decision	0	0			
60th Percentile Total Days to MDUFA IV Decision	0	0			
80th Percentile Total Days to MDUFA IV Decision	0	0			
Maximum Total Days to MDUFA IV Decision	0	0			

**Table 1.8 DMD - OIR - CDRH - PMA Original and Panel-Track Supplements (with Panel Review)  
Performance Metric - Time to MDUFA IV Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number with MDUFA IV Decision	0	0			
<b>Average FDA Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile FDA Days to MDUFA IV Decision	0	0			
40th Percentile FDA Days to MDUFA IV Decision	0	0			
60th Percentile FDA Days to MDUFA IV Decision	0	0			
80th Percentile FDA Days to MDUFA IV Decision	0	0			
Maximum FDA Days to MDUFA IV Decision	0	0			
<b>Average Industry Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	0	0			
80th Percentile Industry Days to MDUFA IV Decision	0	0			
Maximum Industry Days to MDUFA IV Decision	0	0			
<b>Average Total Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile Total Days to MDUFA IV Decision	0	0			
40th Percentile Total Days to MDUFA IV Decision	0	0			
60th Percentile Total Days to MDUFA IV Decision	0	0			
80th Percentile Total Days to MDUFA IV Decision	0	0			
Maximum Total Days to MDUFA IV Decision	0	0			



**Table 1.9 DMD - OIR - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	2	5			
Number with MDUFA IV Decision	0	0			
Number of Withdrawal	0	0			
Number of Not Approvable	0	0			
Number of Deleted	0	0			
Rate of Withdrawal	N/A	N/A			
Rate of Not Approvable	N/A	N/A			

**Table 1.10 DMD - OIR - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	0	0			
Number With MDUFA IV Decision	0	0			
Number of Withdrawal	0	0			
Number of Not Approvable	0	0			
Number of Deleted	0	0			
Rate of Withdrawal	N/A	N/A			
Rate of Not Approvable	N/A	N/A			

**Table 1.11 DMD - OIR - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 1.12 DMD - OIR - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 1.13 DMD - OIR - CDRH - LDT PMA Original and Panel-Track Supplements Metric\***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days
Number of PMAs Filed	0	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	0	0			
MDUFA IV Decision Goal Met	0	0			
PMAs Pending MDUFA IV Decision	0	0			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	N/A	N/A			

\*Includes submission that went to panel

**Table 1.14 DMD - OIR - CDRH - Conventional IVD (Non-LDT) PMA Original and Panel-Track Supplements Metric\***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days
Number of PMAs Filed	2	5			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	0	0			
MDUFA IV Decision Goal Met	0	0			
PMAs Pending MDUFA IV Decision	2	5			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	N/A	N/A			

\*Includes submission that went to panel

## Section 1 PMA Original and Panel-Track Supplements - Division Level Metric

**Table 1.1 DMGP - OIR - CDRH - PMA Original and Panel-Track Supplements - Acceptance Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	8	7			
Closed Before RTA Action	0	0			
Number with Accepted RTA review	8	6			
Number Without a RTA Review and > 15 Days Since Date Received	0	0			
Number Without a RTA Review and <= 15 Days Since Date Received	0	0			
Number Not Accepted for Filing Review	0	1			
Rate of Submissions Not Accepted for Filing Review	0%	14.29%			

**Table 1.2 DMGP - OIR - CDRH - PMA Original and Panel-Track Supplements - Filing Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	8	7			
Number Accepted	8	6			
Completed RTF	8	6			
Number Not Filed	0	0			
Rate of Submissions Not Filed	0%	0%			

**Table 1.3 DMGP - OIR - CDRH - PMA Original and Panel-Track Supplements Substantive Interaction Performance Goal**

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	8	6			
SI Goal Met	8	2			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	4			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	100%	100%			

**Table 1.4 DMGP - OIR - CDRH - PMA Original and Panel-Track Supplements Substantive Interaction Metric - Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number of Substantive Interactions	8	2			
Average Number of FDA Days to Substantive Interaction	83.88	89.50			
20th Percentile FDA Days to Substantive Interaction	86	89			
40th Percentile FDA Days to Substantive Interaction	88	89			
60th Percentile FDA Days to Substantive Interaction	89	90			
80th Percentile FDA Days to Substantive Interaction	90	90			
Maximum FDA Days to Substantive Interaction	90	90			

**Table 1.5 DMGP - OIR - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>
Number of PMAs Filed	8	6			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	7	0			
MDUFA IV Decision Goal Met	7	0			
PMAs Pending MDUFA IV Decision	1	6			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	N/A			

**Table 1.6 DMGP - OIR - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>
Number of PMAs Filed	0	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	0	0			
MDUFA IV Decision Goal Met	0	0			
PMAs Pending MDUFA IV Decision	0	0			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	N/A	N/A			

**Table 1.7 DMGP - OIR - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Time to MDUFA IV Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number with MDUFA IV Decision	7	0			
<b>Average FDA Days to MDUFA IV Decision</b>	115.00	0.00			
20th Percentile FDA Days to MDUFA IV Decision	90	0			
40th Percentile FDA Days to MDUFA IV Decision	99	0			
60th Percentile FDA Days to MDUFA IV Decision	125	0			
80th Percentile FDA Days to MDUFA IV Decision	147	0			
Maximum FDA Days to MDUFA IV Decision	177	0			
<b>Average Industry Days to MDUFA IV Decision</b>	52.57	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	24	0			
60th Percentile Industry Days to MDUFA IV Decision	69	0			
80th Percentile Industry Days to MDUFA IV Decision	75	0			
Maximum Industry Days to MDUFA IV Decision	158	0			
<b>Average Total Days to MDUFA IV Decision</b>	167.57	0.00			
20th Percentile Total Days to MDUFA IV Decision	99	0			
40th Percentile Total Days to MDUFA IV Decision	149	0			
60th Percentile Total Days to MDUFA IV Decision	204	0			
80th Percentile Total Days to MDUFA IV Decision	243	0			
Maximum Total Days to MDUFA IV Decision	252	0			

**Table 1.8 DMGP - OIR - CDRH - PMA Original and Panel-Track Supplements (with Panel Review)  
Performance Metric - Time to MDUFA IV Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number with MDUFA IV Decision	0	0			
<b>Average FDA Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile FDA Days to MDUFA IV Decision	0	0			
40th Percentile FDA Days to MDUFA IV Decision	0	0			
60th Percentile FDA Days to MDUFA IV Decision	0	0			
80th Percentile FDA Days to MDUFA IV Decision	0	0			
Maximum FDA Days to MDUFA IV Decision	0	0			
<b>Average Industry Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	0	0			
80th Percentile Industry Days to MDUFA IV Decision	0	0			
Maximum Industry Days to MDUFA IV Decision	0	0			
<b>Average Total Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile Total Days to MDUFA IV Decision	0	0			
40th Percentile Total Days to MDUFA IV Decision	0	0			
60th Percentile Total Days to MDUFA IV Decision	0	0			
80th Percentile Total Days to MDUFA IV Decision	0	0			
Maximum Total Days to MDUFA IV Decision	0	0			

**Table 1.9 DMGP - OIR - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	8	6			
Number with MDUFA IV Decision	7	0			
Number of Withdrawal	3	0			
Number of Not Approvable	0	0			
Number of Deleted	0	0			
Rate of Withdrawal	42.86%	N/A			
Rate of Not Approvable	0%	N/A			

**Table 1.10 DMGP - OIR - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	0	0			
Number With MDUFA IV Decision	0	0			
Number of Withdrawal	0	0			
Number of Not Approvable	0	0			
Number of Deleted	0	0			
Rate of Withdrawal	N/A	N/A			
Rate of Not Approvable	N/A	N/A			

**Table 1.11 DMGP - OIR - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 1.12 DMGP - OIR - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 1.13 DMGP - OIR - CDRH - LDT PMA Original and Panel-Track Supplements Metric\***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days
Number of PMAs Filed	1	2			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	1	0			
MDUFA IV Decision Goal Met	1	0			
PMAs Pending MDUFA IV Decision	0	2			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	N/A			

\*Includes submission that went to panel

**Table 1.14 DMGP - OIR - CDRH - Conventional IVD (Non-LDT) PMA Original and Panel-Track Supplements Metric\***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days
Number of PMAs Filed	7	4			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	6	0			
MDUFA IV Decision Goal Met	6	0			
PMAs Pending MDUFA IV Decision	1	4			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	N/A			

\*Includes submission that went to panel



## Section 1 PMA Original and Panel-Track Supplements - Division Level Metric

**Table 1.1 DRH - OIR - CDRH - PMA Original and Panel-Track Supplements - Acceptance Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	1	0			
Closed Before RTA Action	0	0			
Number with Accepted RTA review	1	0			
Number Without a RTA Review and > 15 Days Since Date Received	0	0			
Number Without a RTA Review and <= 15 Days Since Date Received	0	0			
Number Not Accepted for Filing Review	0	0			
Rate of Submissions Not Accepted for Filing Review	0%	N/A			

**Table 1.2 DRH - OIR - CDRH - PMA Original and Panel-Track Supplements - Filing Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	1	0			
Number Accepted	1	0			
Completed RTF	1	0			
Number Not Filed	0	0			
Rate of Submissions Not Filed	0%	N/A			

**Table 1.3 DRH - OIR - CDRH - PMA Original and Panel-Track Supplements Substantive Interaction Performance Goal**

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	1	0			
SI Goal Met	1	0			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	0			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	100%	N/A			

**Table 1.4 DRH - OIR - CDRH - PMA Original and Panel-Track Supplements Substantive Interaction Metric - Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number of Substantive Interactions	1	0			
Average Number of FDA Days to Substantive Interaction	63.00	0.00			
20th Percentile FDA Days to Substantive Interaction	63	0			
40th Percentile FDA Days to Substantive Interaction	63	0			
60th Percentile FDA Days to Substantive Interaction	63	0			
80th Percentile FDA Days to Substantive Interaction	63	0			
Maximum FDA Days to Substantive Interaction	63	0			

**Table 1.5 DRH - OIR - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>
Number of PMAs Filed	1	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	1	0			
MDUFA IV Decision Goal Met	1	0			
PMAs Pending MDUFA IV Decision	0	0			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	N/A			

**Table 1.6 DRH - OIR - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>
Number of PMAs Filed	0	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	0	0			
MDUFA IV Decision Goal Met	0	0			
PMAs Pending MDUFA IV Decision	0	0			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	N/A	N/A			

**Table 1.7 DRH - OIR - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Time to MDUFA IV Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number with MDUFA IV Decision	1	0			
<b>Average FDA Days to MDUFA IV Decision</b>	63.00	0.00			
20th Percentile FDA Days to MDUFA IV Decision	63	0			
40th Percentile FDA Days to MDUFA IV Decision	63	0			
60th Percentile FDA Days to MDUFA IV Decision	63	0			
80th Percentile FDA Days to MDUFA IV Decision	63	0			
Maximum FDA Days to MDUFA IV Decision	63	0			
<b>Average Industry Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	0	0			
80th Percentile Industry Days to MDUFA IV Decision	0	0			
Maximum Industry Days to MDUFA IV Decision	0	0			
<b>Average Total Days to MDUFA IV Decision</b>	63.00	0.00			
20th Percentile Total Days to MDUFA IV Decision	63	0			
40th Percentile Total Days to MDUFA IV Decision	63	0			
60th Percentile Total Days to MDUFA IV Decision	63	0			
80th Percentile Total Days to MDUFA IV Decision	63	0			
Maximum Total Days to MDUFA IV Decision	63	0			

**Table 1.8 DRH - OIR - CDRH - PMA Original and Panel-Track Supplements (with Panel Review)  
Performance Metric - Time to MDUFA IV Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number with MDUFA IV Decision	0	0			
<b>Average FDA Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile FDA Days to MDUFA IV Decision	0	0			
40th Percentile FDA Days to MDUFA IV Decision	0	0			
60th Percentile FDA Days to MDUFA IV Decision	0	0			
80th Percentile FDA Days to MDUFA IV Decision	0	0			
Maximum FDA Days to MDUFA IV Decision	0	0			
<b>Average Industry Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	0	0			
80th Percentile Industry Days to MDUFA IV Decision	0	0			
Maximum Industry Days to MDUFA IV Decision	0	0			
<b>Average Total Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile Total Days to MDUFA IV Decision	0	0			
40th Percentile Total Days to MDUFA IV Decision	0	0			
60th Percentile Total Days to MDUFA IV Decision	0	0			
80th Percentile Total Days to MDUFA IV Decision	0	0			
Maximum Total Days to MDUFA IV Decision	0	0			

**Table 1.9 DRH - OIR - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	1	0			
Number with MDUFA IV Decision	1	0			
Number of Withdrawal	1	0			
Number of Not Approvable	0	0			
Number of Deleted	0	0			
Rate of Withdrawal	100%	N/A			
Rate of Not Approvable	0%	N/A			

**Table 1.10 DRH - OIR - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	0	0			
Number With MDUFA IV Decision	0	0			
Number of Withdrawal	0	0			
Number of Not Approvable	0	0			
Number of Deleted	0	0			
Rate of Withdrawal	N/A	N/A			
Rate of Not Approvable	N/A	N/A			

**Table 1.11 DRH - OIR - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 1.12 DRH - OIR - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 1.13 DRH - OIR - CDRH - LDT PMA Original and Panel-Track Supplements Metric\***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days
Number of PMAs Filed	0	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	0	0			
MDUFA IV Decision Goal Met	0	0			
PMAs Pending MDUFA IV Decision	0	0			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	N/A	N/A			

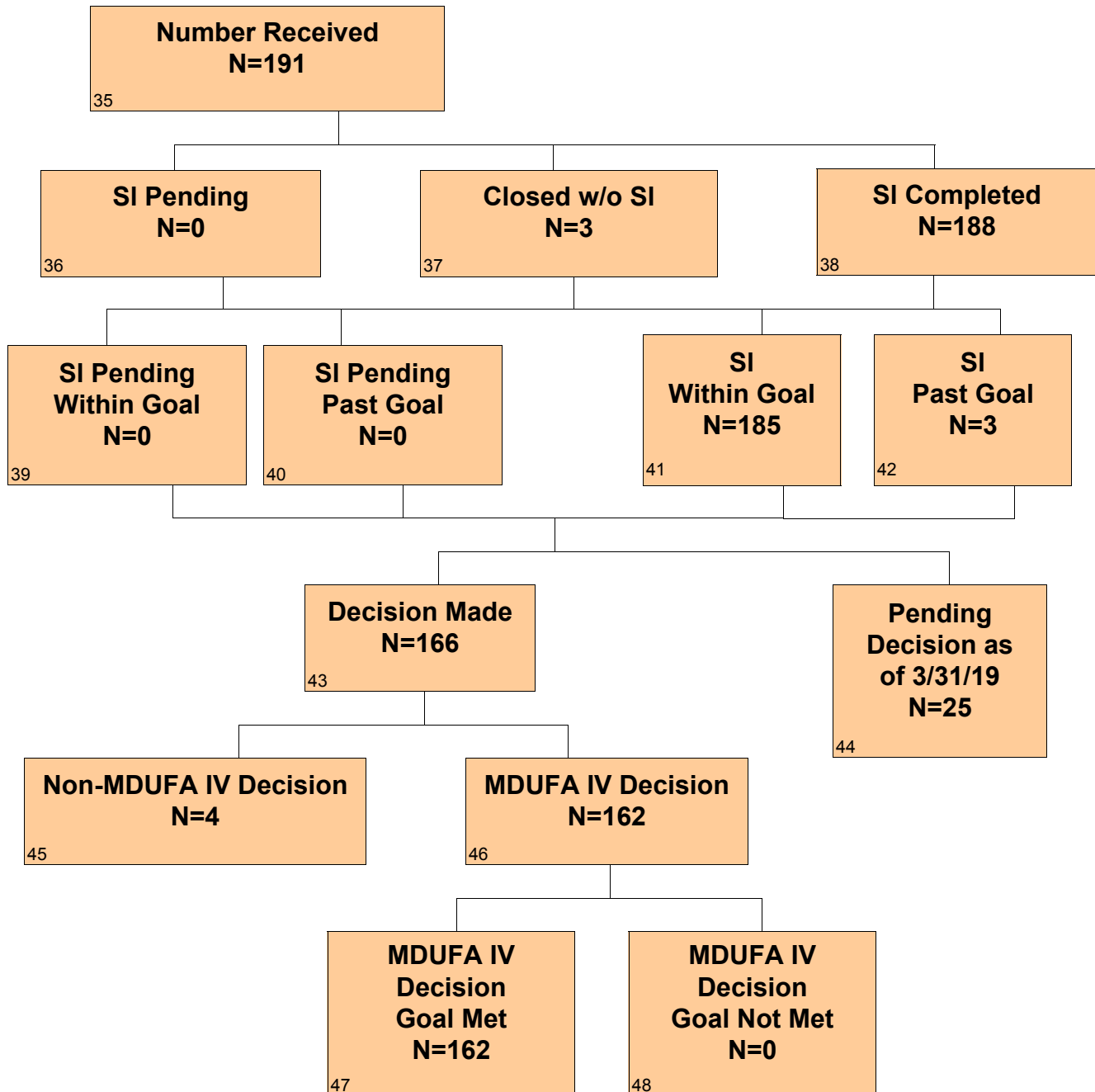
\*Includes submission that went to panel

**Table 1.14 DRH - OIR - CDRH - Conventional IVD (Non-LDT) PMA Original and Panel-Track Supplements Metric\***

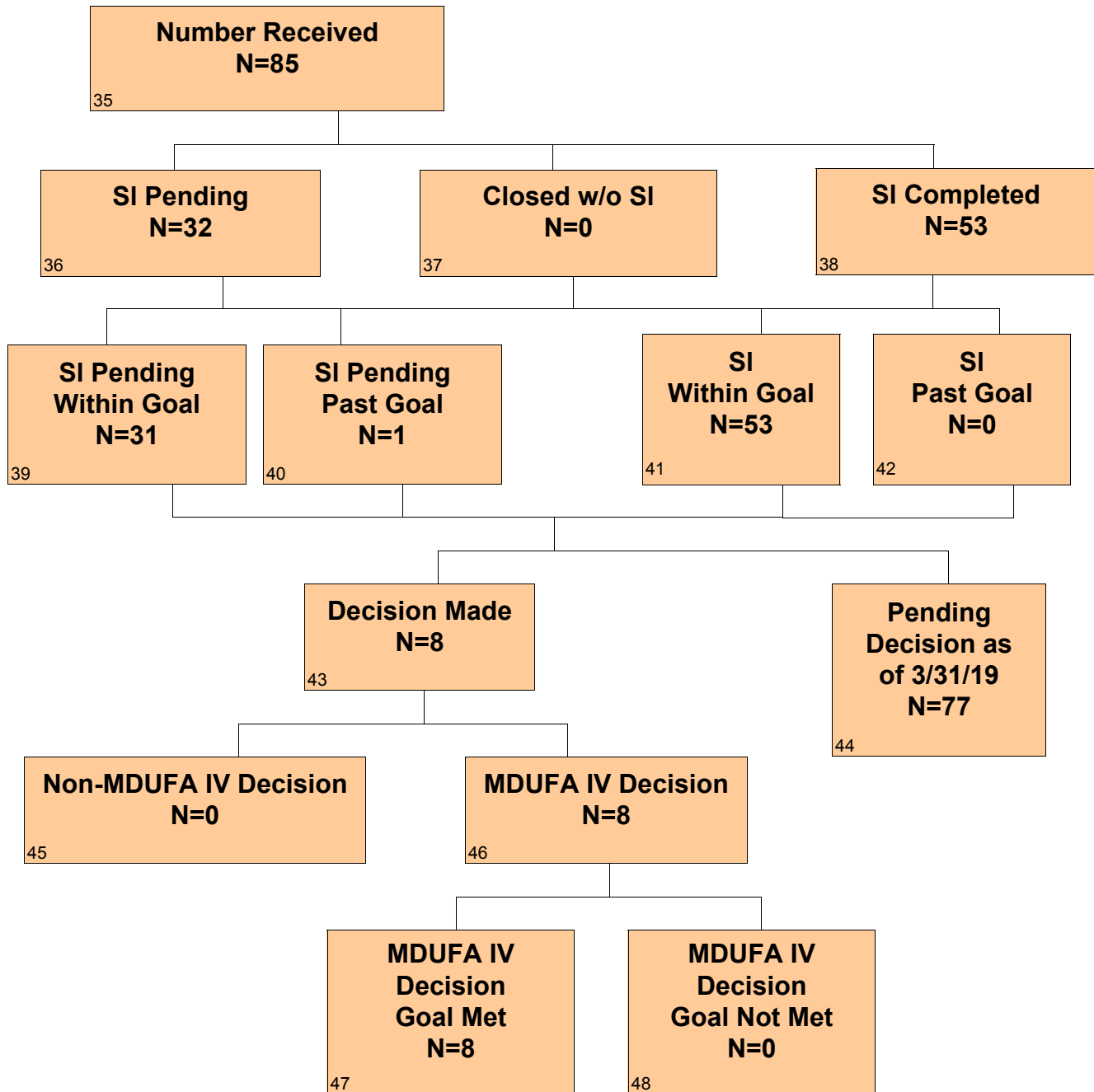
Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days
Number of PMAs Filed	0	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	0	0			
MDUFA IV Decision Goal Met	0	0			
PMAs Pending MDUFA IV Decision	0	0			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	N/A	N/A			

\*Includes submission that went to panel

# CDRH PMA 180 Day Supplements - FY 2018 as of 3/31/19



# CDRH PMA 180 Day Supplements - FY 2019 as of 3/31/19





## Section 2 PMA 180-Day Supplements - Center Level Metric

Table 2.1 CDRH - PMA 180-Day Supplements Substantive Interaction Goal

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	191	85			
SI Goal Met	185	53			
SI Goal Not Met	3	0			
SI Pending Within Goal	0	31			
SI Pending Past Goal	0	1			
Closed Without SI	3	0			
Current SI Performance Percent Goal Met	98.40%	98.15%			

Table 2.2 CDRH - PMA 180-Day Supplements MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days
Supplements Received	191	85			
Non-MDUFA IV Decision	4	0			
MDUFA IV Decision	162	8			
MDUFA IV Decision Goal Met	162	8			
Supplements Pending MDUFA IV Decision	25	77			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

Table 2.3 CDRH - PMA 180-Day Supplements Performance Metric - Rate of Not Approvable

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	191	85			
Number with MDUFA IV Decision	162	8			
Number of Not Approvable	8	0			
Rate of Not Approvable	4.94%	0%			

Table 2.4 CDRH - PMA 180-Day Supplements Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

## Section 2 PMA 180-Day Supplements - Office Level Metric

Table 2.1 ODE - CDRH - PMA 180-Day Supplements Substantive Interaction Goal

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	154	74			
SI Goal Met	149	47			
SI Goal Not Met	2	0			
SI Pending Within Goal	0	26			
SI Pending Past Goal	0	1			
Closed Without SI	3	0			
Current SI Performance Percent Goal Met	98.68%	97.92%			

Table 2.2 ODE - CDRH - PMA 180-Day Supplements MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 180 FDA Days	95% Within 180 FDA Days	95% Within 180 FDA Days	95% Within 180 FDA Days	95% Within 180 FDA Days
Supplements Received	154	74			
Non-MDUFA IV Decision	3	0			
MDUFA IV Decision	137	6			
MDUFA IV Decision Goal Met	137	6			
Supplements Pending MDUFA IV Decision	14	68			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

Table 2.3 ODE - CDRH - PMA 180-Day Supplements Performance Metric - Rate of Not Approvable

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	154	74			
Number with MDUFA IV Decision	137	6			
Number of Not Approvable	7	0			
Rate of Not Approvable	5.11%	0%			

Table 2.4 ODE - CDRH - PMA 180-Day Supplements Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

## Section 2 PMA 180-Day Supplements - Office Level Metric

Table 2.1 OIR - CDRH - PMA 180-Day Supplements Substantive Interaction Goal

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	37	11			
SI Goal Met	36	6			
SI Goal Not Met	1	0			
SI Pending Within Goal	0	5			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	97.30%	100%			

Table 2.2 OIR - CDRH - PMA 180-Day Supplements MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 180 FDA Days	95% Within 180 FDA Days	95% Within 180 FDA Days	95% Within 180 FDA Days	95% Within 180 FDA Days
Supplements Received	37	11			
Non-MDUFA IV Decision	1	0			
MDUFA IV Decision	25	2			
MDUFA IV Decision Goal Met	25	2			
Supplements Pending MDUFA IV Decision	11	9			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

Table 2.3 OIR - CDRH - PMA 180-Day Supplements Performance Metric - Rate of Not Approvable

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	37	11			
Number with MDUFA IV Decision	25	2			
Number of Not Approvable	1	0			
Rate of Not Approvable	4.00%	0%			

Table 2.4 OIR - CDRH - PMA 180-Day Supplements Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

## Section 2 PMA 180-Day Supplements - Division Level Metric

Table 2.1 DAGRID - ODE - CDRH - PMA 180-Day Supplements Substantive Interaction Goal

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	9	6			
SI Goal Met	8	4			
SI Goal Not Met	1	0			
SI Pending Within Goal	0	2			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	88.89%	100%			

Table 2.2 DAGRID - ODE - CDRH - PMA 180-Day Supplements MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days
Supplements Received	9	6			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	8	2			
MDUFA IV Decision Goal Met	8	2			
Supplements Pending MDUFA IV Decision	1	4			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

Table 2.3 DAGRID - ODE - CDRH - PMA 180-Day Supplements Performance Metric - Rate of Not Approvable

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	9	6			
Number with MDUFA IV Decision	8	2			
Number of Not Approvable	1	0			
Rate of Not Approvable	12.50%	0%			

Table 2.4 DAGRID - ODE - CDRH - PMA 180-Day Supplements Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

## Section 2 PMA 180-Day Supplements - Division Level Metric

Table 2.1 DCD - ODE - CDRH - PMA 180-Day Supplements Substantive Interaction Goal

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	94	35			
SI Goal Met	91	23			
SI Goal Not Met	1	0			
SI Pending Within Goal	0	12			
SI Pending Past Goal	0	0			
Closed Without SI	2	0			
Current SI Performance Percent Goal Met	98.91%	100%			

Table 2.2 DCD - ODE - CDRH - PMA 180-Day Supplements MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days
Supplements Received	94	35			
Non-MDUFA IV Decision	2	0			
MDUFA IV Decision	88	2			
MDUFA IV Decision Goal Met	88	2			
Supplements Pending MDUFA IV Decision	4	33			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

Table 2.3 DCD - ODE - CDRH - PMA 180-Day Supplements Performance Metric - Rate of Not Approvable

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	94	35			
Number with MDUFA IV Decision	88	2			
Number of Not Approvable	4	0			
Rate of Not Approvable	4.55%	0%			

Table 2.4 DCD - ODE - CDRH - PMA 180-Day Supplements Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

## Section 2 PMA 180-Day Supplements - Division Level Metric

Table 2.1 DNPMD - ODE - CDRH - PMA 180-Day Supplements Substantive Interaction Goal

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	13	8			
SI Goal Met	12	2			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	6			
SI Pending Past Goal	0	0			
Closed Without SI	1	0			
Current SI Performance Percent Goal Met	100%	100%			

Table 2.2 DNPMD - ODE - CDRH - PMA 180-Day Supplements MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days
Supplements Received	13	8			
Non-MDUFA IV Decision	1	0			
MDUFA IV Decision	11	0			
MDUFA IV Decision Goal Met	11	0			
Supplements Pending MDUFA IV Decision	1	8			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	N/A			

Table 2.3 DNPMD - ODE - CDRH - PMA 180-Day Supplements Performance Metric - Rate of Not Approvable

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	13	8			
Number with MDUFA IV Decision	11	0			
Number of Not Approvable	2	0			
Rate of Not Approvable	18.18%	N/A			

Table 2.4 DNPMD - ODE - CDRH - PMA 180-Day Supplements Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

## Section 2 PMA 180-Day Supplements - Division Level Metric

Table 2.1 DOD - ODE - CDRH - PMA 180-Day Supplements Substantive Interaction Goal

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	1	3			
SI Goal Met	1	3			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	0			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	100%	100%			

Table 2.2 DOD - ODE - CDRH - PMA 180-Day Supplements MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days
Supplements Received	1	3			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	1	2			
MDUFA IV Decision Goal Met	1	2			
Supplements Pending MDUFA IV Decision	0	1			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

Table 2.3 DOD - ODE - CDRH - PMA 180-Day Supplements Performance Metric - Rate of Not Approvable

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	1	3			
Number with MDUFA IV Decision	1	2			
Number of Not Approvable	0	0			
Rate of Not Approvable	0%	0%			

Table 2.4 DOD - ODE - CDRH - PMA 180-Day Supplements Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

## Section 2 PMA 180-Day Supplements - Division Level Metric

Table 2.1 DOED - ODE - CDRH - PMA 180-Day Supplements Substantive Interaction Goal

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	16	14			
SI Goal Met	16	13			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	1			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	100%	100%			

Table 2.2 DOED - ODE - CDRH - PMA 180-Day Supplements MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days
Supplements Received	16	14			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	13	0			
MDUFA IV Decision Goal Met	13	0			
Supplements Pending MDUFA IV Decision	3	14			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	N/A			

Table 2.3 DOED - ODE - CDRH - PMA 180-Day Supplements Performance Metric - Rate of Not Approvable

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	16	14			
Number with MDUFA IV Decision	13	0			
Number of Not Approvable	0	0			
Rate of Not Approvable	0%	N/A			

Table 2.4 DOED - ODE - CDRH - PMA 180-Day Supplements Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			



## Section 2 PMA 180-Day Supplements - Division Level Metric

Table 2.1 DRGUD - ODE - CDRH - PMA 180-Day Supplements Substantive Interaction Goal

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	10	1			
SI Goal Met	10	0			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	1			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	100%	N/A			

Table 2.2 DRGUD - ODE - CDRH - PMA 180-Day Supplements MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days
Supplements Received	10	1			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	10	0			
MDUFA IV Decision Goal Met	10	0			
Supplements Pending MDUFA IV Decision	0	1			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	N/A			

Table 2.3 DRGUD - ODE - CDRH - PMA 180-Day Supplements Performance Metric - Rate of Not Approvable

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	10	1			
Number with MDUFA IV Decision	10	0			
Number of Not Approvable	0	0			
Rate of Not Approvable	0%	N/A			

Table 2.4 DRGUD - ODE - CDRH - PMA 180-Day Supplements Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

## Section 2 PMA 180-Day Supplements - Division Level Metric

Table 2.1 DSD - ODE - CDRH - PMA 180-Day Supplements Substantive Interaction Goal

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	11	7			
SI Goal Met	11	2			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	4			
SI Pending Past Goal	0	1			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	100%	66.67%			

Table 2.2 DSD - ODE - CDRH - PMA 180-Day Supplements MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days
Supplements Received	11	7			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	6	0			
MDUFA IV Decision Goal Met	6	0			
Supplements Pending MDUFA IV Decision	5	7			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	N/A			

Table 2.3 DSD - ODE - CDRH - PMA 180-Day Supplements Performance Metric - Rate of Not Approvable

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	11	7			
Number with MDUFA IV Decision	6	0			
Number of Not Approvable	0	0			
Rate of Not Approvable	0%	N/A			

Table 2.4 DSD - ODE - CDRH - PMA 180-Day Supplements Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

## Section 2 PMA 180-Day Supplements - Division Level Metric

Table 2.1 DCTD - OIR - CDRH - PMA 180-Day Supplements Substantive Interaction Goal

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	11	3			
SI Goal Met	11	2			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	1			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	100%	100%			

Table 2.2 DCTD - OIR - CDRH - PMA 180-Day Supplements MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days
Supplements Received	11	3			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	9	0			
MDUFA IV Decision Goal Met	9	0			
Supplements Pending MDUFA IV Decision	2	3			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	N/A			

Table 2.3 DCTD - OIR - CDRH - PMA 180-Day Supplements Performance Metric - Rate of Not Approvable

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	11	3			
Number with MDUFA IV Decision	9	0			
Number of Not Approvable	0	0			
Rate of Not Approvable	0%	N/A			

Table 2.4 DCTD - OIR - CDRH - PMA 180-Day Supplements Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

## Section 2 PMA 180-Day Supplements - Division Level Metric

Table 2.1 DIHD - OIR - CDRH - PMA 180-Day Supplements Substantive Interaction Goal

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	3	1			
SI Goal Met	3	1			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	0			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	100%	100%			

Table 2.2 DIHD - OIR - CDRH - PMA 180-Day Supplements MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days
Supplements Received	3	1			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	0	1			
MDUFA IV Decision Goal Met	0	1			
Supplements Pending MDUFA IV Decision	3	0			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	N/A	100%			

Table 2.3 DIHD - OIR - CDRH - PMA 180-Day Supplements Performance Metric - Rate of Not Approvable

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	3	1			
Number with MDUFA IV Decision	0	1			
Number of Not Approvable	0	0			
Rate of Not Approvable	N/A	0%			

Table 2.4 DIHD - OIR - CDRH - PMA 180-Day Supplements Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

## Section 2 PMA 180-Day Supplements - Division Level Metric

Table 2.1 DMD - OIR - CDRH - PMA 180-Day Supplements Substantive Interaction Goal

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	8	0			
SI Goal Met	8	0			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	0			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	100%	N/A			

Table 2.2 DMD - OIR - CDRH - PMA 180-Day Supplements MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days
Supplements Received	8	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	5	0			
MDUFA IV Decision Goal Met	5	0			
Supplements Pending MDUFA IV Decision	3	0			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	N/A			

Table 2.3 DMD - OIR - CDRH - PMA 180-Day Supplements Performance Metric - Rate of Not Approvable

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	8	0			
Number with MDUFA IV Decision	5	0			
Number of Not Approvable	0	0			
Rate of Not Approvable	0%	N/A			

Table 2.4 DMD - OIR - CDRH - PMA 180-Day Supplements Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

## Section 2 PMA 180-Day Supplements - Division Level Metric

Table 2.1 DMGP - OIR - CDRH - PMA 180-Day Supplements Substantive Interaction Goal

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	13	6			
SI Goal Met	12	2			
SI Goal Not Met	1	0			
SI Pending Within Goal	0	4			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	92.31%	100%			

Table 2.2 DMGP - OIR - CDRH - PMA 180-Day Supplements MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days
Supplements Received	13	6			
Non-MDUFA IV Decision	1	0			
MDUFA IV Decision	10	0			
MDUFA IV Decision Goal Met	10	0			
Supplements Pending MDUFA IV Decision	2	6			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	N/A			

Table 2.3 DMGP - OIR - CDRH - PMA 180-Day Supplements Performance Metric - Rate of Not Approvable

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	13	6			
Number with MDUFA IV Decision	10	0			
Number of Not Approvable	1	0			
Rate of Not Approvable	10.00%	N/A			

Table 2.4 DMGP - OIR - CDRH - PMA 180-Day Supplements Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

## Section 2 PMA 180-Day Supplements - Division Level Metric

Table 2.1 DRH - OIR - CDRH - PMA 180-Day Supplements Substantive Interaction Goal

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	2	1			
SI Goal Met	2	1			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	0			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	100%	100%			

Table 2.2 DRH - OIR - CDRH - PMA 180-Day Supplements MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days
Supplements Received	2	1			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	1	1			
MDUFA IV Decision Goal Met	1	1			
Supplements Pending MDUFA IV Decision	1	0			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

Table 2.3 DRH - OIR - CDRH - PMA 180-Day Supplements Performance Metric - Rate of Not Approvable

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	2	1			
Number with MDUFA IV Decision	1	1			
Number of Not Approvable	0	0			
Rate of Not Approvable	0%	0%			

Table 2.4 DRH - OIR - CDRH - PMA 180-Day Supplements Performance Metric - Submissions Missing Performance Goal

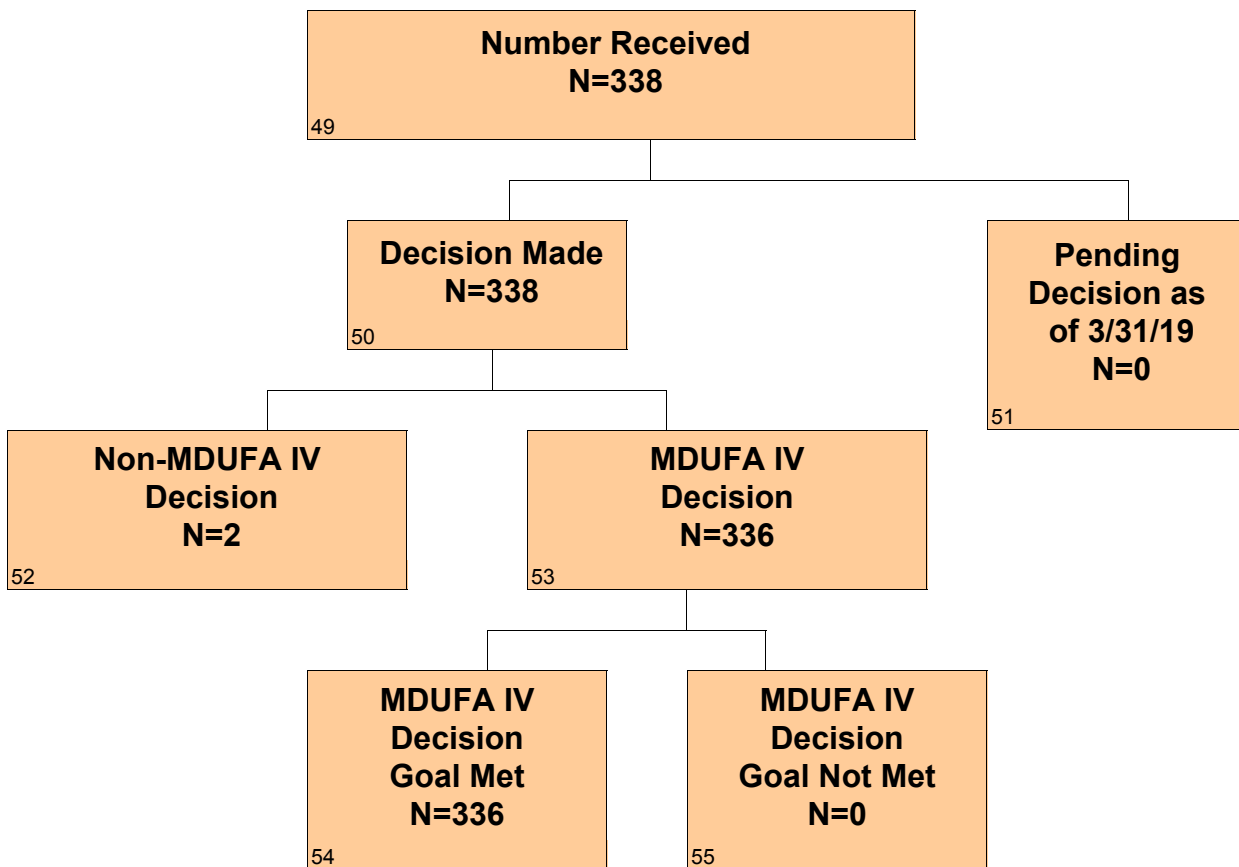
Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

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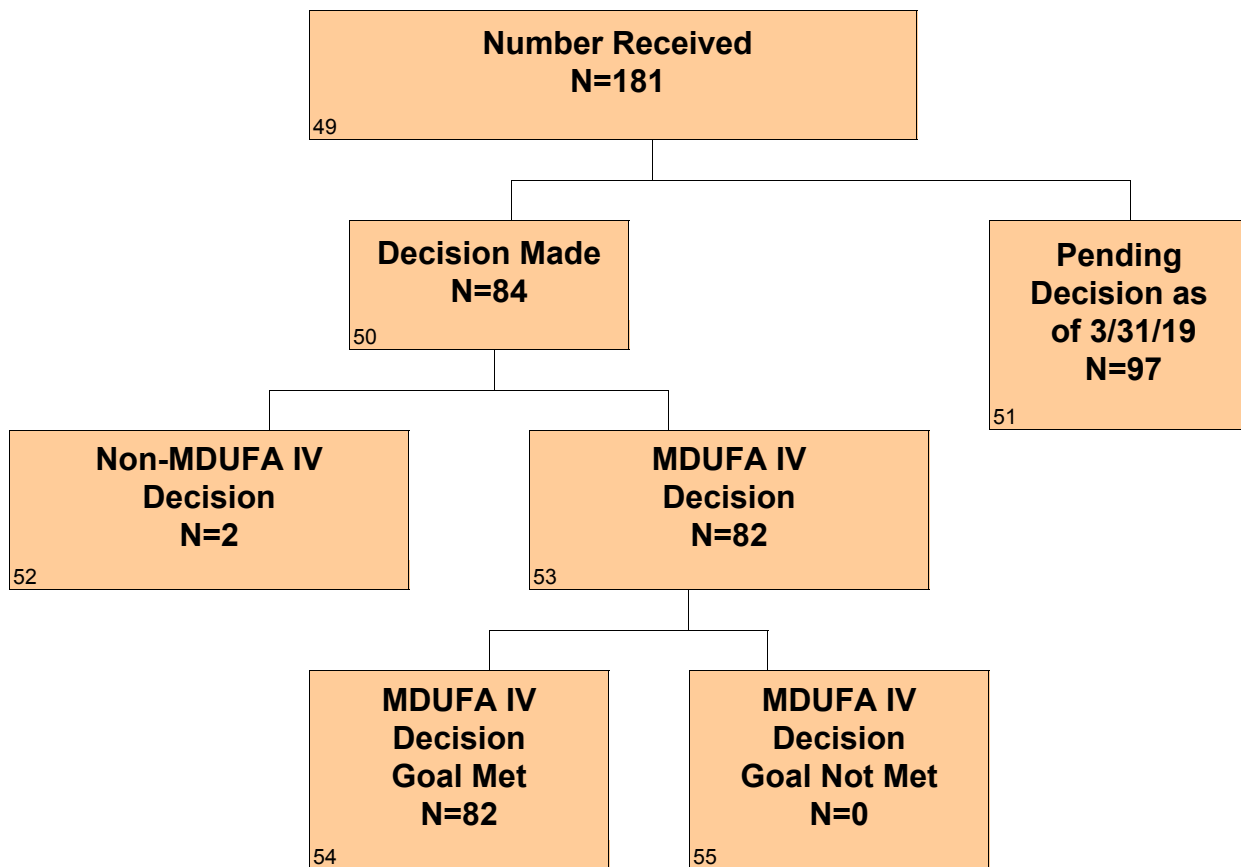
# CDRH PMA Real Time Supplements - FY 2018 as of 3/31/19

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# CDRH PMA Real Time Supplements - FY 2019 as of 3/31/19

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### Section 3 PMA Real-Time Supplements - Center Level Metric

Table 3.1 CDRH - PMA Real-Time Supplements MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
Supplements Received	338	181			
Non-MDUFA IV Decision	2	2			
MDUFA IV Decision	336	82			
MDUFA IV Decision Goal Met	336	82			
Supplements Pending MDUFA IV Decision	0	97			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

Table 3.2 CDRH - PMA Real-Time Supplements Performance Metric - Rate of Not Approvable

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	338	181			
Number With MDUFA IV Decision	336	82			
Number of Not Approvable	20	8			
Rate of Not Approvable	5.95%	9.76%			

Table 3.3 CDRH - PMA Real-Time Supplements Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

### Section 3 PMA Real-Time Supplements - Office Level Metric

Table 3.1 ODE - CDRH - PMA Real-Time Supplements MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
Supplements Received	243	159			
Non-MDUFA IV Decision	1	2			
MDUFA IV Decision	242	72			
MDUFA IV Decision Goal Met	242	72			
Supplements Pending MDUFA IV Decision	0	85			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

Table 3.2 ODE - CDRH - PMA Real-Time Supplements Performance Metric - Rate of Not Approvable

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	243	159			
Number With MDUFA IV Decision	242	72			
Number of Not Approvable	20	8			
Rate of Not Approvable	8.26%	11.11%			

Table 3.3 ODE - CDRH - PMA Real-Time Supplements Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

### Section 3 PMA Real-Time Supplements - Office Level Metric

**Table 3.1 OIR - CDRH - PMA Real-Time Supplements MDUFA IV Decision Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
Supplements Received	95	22			
Non-MDUFA IV Decision	1	0			
MDUFA IV Decision	94	10			
MDUFA IV Decision Goal Met	94	10			
Supplements Pending MDUFA IV Decision	0	12			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

**Table 3.2 OIR - CDRH - PMA Real-Time Supplements Performance Metric - Rate of Not Approvable**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	95	22			
Number With MDUFA IV Decision	94	10			
Number of Not Approvable	0	0			
Rate of Not Approvable	0%	0%			

**Table 3.3 OIR - CDRH - PMA Real-Time Supplements Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Section 3 PMA Real-Time Supplements - Division Level Metric**

**Table 3.1 DAGRID - ODE - CDRH - PMA Real-Time Supplements MDUFA IV Decision Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
Supplements Received	9	5			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	9	5			
MDUFA IV Decision Goal Met	9	5			
Supplements Pending MDUFA IV Decision	0	0			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

**Table 3.2 DAGRID - ODE - CDRH - PMA Real-Time Supplements Performance Metric - Rate of Not Approvable**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	9	5			
Number with MDUFA IV Decision	9	5			
Number of Not Approvable	0	0			
Rate of Not Approvable	0%	0%			

**Table 3.3 DAGRID - ODE - CDRH - PMA Real-Time Supplements Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Section 3 PMA Real-Time Supplements - Division Level Metric**

**Table 3.1 DCD - ODE - CDRH - PMA Real-Time Supplements MDUFA IV Decision Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
Supplements Received	154	98			
Non-MDUFA IV Decision	0	1			
MDUFA IV Decision	154	46			
MDUFA IV Decision Goal Met	154	46			
Supplements Pending MDUFA IV Decision	0	51			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

**Table 3.2 DCD - ODE - CDRH - PMA Real-Time Supplements Performance Metric - Rate of Not Approvable**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	154	98			
Number with MDUFA IV Decision	154	46			
Number of Not Approvable	12	7			
Rate of Not Approvable	7.79%	15.22%			

**Table 3.3 DCD - ODE - CDRH - PMA Real-Time Supplements Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Section 3 PMA Real-Time Supplements - Division Level Metric**

**Table 3.1 DNPMD - ODE - CDRH - PMA Real-Time Supplements MDUFA IV Decision Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
Supplements Received	16	15			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	16	8			
MDUFA IV Decision Goal Met	16	8			
Supplements Pending MDUFA IV Decision	0	7			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

**Table 3.2 DNPMD - ODE - CDRH - PMA Real-Time Supplements Performance Metric - Rate of Not Approvable**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	16	15			
Number with MDUFA IV Decision	16	8			
Number of Not Approvable	0	0			
Rate of Not Approvable	0%	0%			

**Table 3.3 DNPMD - ODE - CDRH - PMA Real-Time Supplements Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			



**Section 3 PMA Real-Time Supplements - Division Level Metric**

**Table 3.1 DOD - ODE - CDRH - PMA Real-Time Supplements MDUFA IV Decision Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
Supplements Received	17	7			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	17	4			
MDUFA IV Decision Goal Met	17	4			
Supplements Pending MDUFA IV Decision	0	3			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

**Table 3.2 DOD - ODE - CDRH - PMA Real-Time Supplements Performance Metric - Rate of Not Approvable**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	17	7			
Number with MDUFA IV Decision	17	4			
Number of Not Approvable	2	1			
Rate of Not Approvable	11.76%	25.00%			

**Table 3.3 DOD - ODE - CDRH - PMA Real-Time Supplements Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

### Section 3 PMA Real-Time Supplements - Division Level Metric

**Table 3.1 DOED - ODE - CDRH - PMA Real-Time Supplements MDUFA IV Decision Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
Supplements Received	19	15			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	19	2			
MDUFA IV Decision Goal Met	19	2			
Supplements Pending MDUFA IV Decision	0	13			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

**Table 3.2 DOED - ODE - CDRH - PMA Real-Time Supplements Performance Metric - Rate of Not Approvable**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	19	15			
Number with MDUFA IV Decision	19	2			
Number of Not Approvable	1	0			
Rate of Not Approvable	5.26%	0%			

**Table 3.3 DOED - ODE - CDRH - PMA Real-Time Supplements Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Section 3 PMA Real-Time Supplements - Division Level Metric**

**Table 3.1 DRGUD - ODE - CDRH - PMA Real-Time Supplements MDUFA IV Decision Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
Supplements Received	15	12			
Non-MDUFA IV Decision	0	1			
MDUFA IV Decision	15	4			
MDUFA IV Decision Goal Met	15	4			
Supplements Pending MDUFA IV Decision	0	7			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

**Table 3.2 DRGUD - ODE - CDRH - PMA Real-Time Supplements Performance Metric - Rate of Not Approvable**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	15	12			
Number with MDUFA IV Decision	15	4			
Number of Not Approvable	1	0			
Rate of Not Approvable	6.67%	0%			

**Table 3.3 DRGUD - ODE - CDRH - PMA Real-Time Supplements Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

### Section 3 PMA Real-Time Supplements - Division Level Metric

**Table 3.1 DSD - ODE - CDRH - PMA Real-Time Supplements MDUFA IV Decision Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
Supplements Received	13	7			
Non-MDUFA IV Decision	1	0			
MDUFA IV Decision	12	3			
MDUFA IV Decision Goal Met	12	3			
Supplements Pending MDUFA IV Decision	0	4			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

**Table 3.2 DSD - ODE - CDRH - PMA Real-Time Supplements Performance Metric - Rate of Not Approvable**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	13	7			
Number with MDUFA IV Decision	12	3			
Number of Not Approvable	4	0			
Rate of Not Approvable	33.33%	0%			

**Table 3.3 DSD - ODE - CDRH - PMA Real-Time Supplements Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Section 3 PMA Real-Time Supplements - Division Level Metric**

**Table 3.1 DCTD - OIR - CDRH - PMA Real-Time Supplements MDUFA IV Decision Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
Supplements Received	28	7			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	28	4			
MDUFA IV Decision Goal Met	28	4			
Supplements Pending MDUFA IV Decision	0	3			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

**Table 3.2 DCTD - OIR - CDRH - PMA Real-Time Supplements Performance Metric - Rate of Not Approvable**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	28	7			
Number with MDUFA IV Decision	28	4			
Number of Not Approvable	0	0			
Rate of Not Approvable	0%	0%			

**Table 3.3 DCTD - OIR - CDRH - PMA Real-Time Supplements Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

### Section 3 PMA Real-Time Supplements - Division Level Metric

**Table 3.1 DIHD - OIR - CDRH - PMA Real-Time Supplements MDUFA IV Decision Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
Supplements Received	18	3			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	18	0			
MDUFA IV Decision Goal Met	18	0			
Supplements Pending MDUFA IV Decision	0	3			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	N/A			

**Table 3.2 DIHD - OIR - CDRH - PMA Real-Time Supplements Performance Metric - Rate of Not Approvable**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	18	3			
Number with MDUFA IV Decision	18	0			
Number of Not Approvable	0	0			
Rate of Not Approvable	0%	N/A			

**Table 3.3 DIHD - OIR - CDRH - PMA Real-Time Supplements Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Section 3 PMA Real-Time Supplements - Division Level Metric**

**Table 3.1 DMD - OIR - CDRH - PMA Real-Time Supplements MDUFA IV Decision Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
Supplements Received	38	10			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	38	4			
MDUFA IV Decision Goal Met	38	4			
Supplements Pending MDUFA IV Decision	0	6			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

**Table 3.2 DMD - OIR - CDRH - PMA Real-Time Supplements Performance Metric - Rate of Not Approvable**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	38	10			
Number with MDUFA IV Decision	38	4			
Number of Not Approvable	0	0			
Rate of Not Approvable	0%	0%			

**Table 3.3 DMD - OIR - CDRH - PMA Real-Time Supplements Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

### Section 3 PMA Real-Time Supplements - Division Level Metric

**Table 3.1 DMGP - OIR - CDRH - PMA Real-Time Supplements MDUFA IV Decision Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
Supplements Received	9	2			
Non-MDUFA IV Decision	1	0			
MDUFA IV Decision	8	2			
MDUFA IV Decision Goal Met	8	2			
Supplements Pending MDUFA IV Decision	0	0			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

**Table 3.2 DMGP - OIR - CDRH - PMA Real-Time Supplements Performance Metric - Rate of Not Approvable**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	9	2			
Number with MDUFA IV Decision	8	2			
Number of Not Approvable	0	0			
Rate of Not Approvable	0%	0%			

**Table 3.3 DMGP - OIR - CDRH - PMA Real-Time Supplements Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			



**Section 3 PMA Real-Time Supplements - Division Level Metric**

**Table 3.1 DRH - OIR - CDRH - PMA Real-Time Supplements MDUFA IV Decision Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
Supplements Received	2	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	2	0			
MDUFA IV Decision Goal Met	2	0			
Supplements Pending MDUFA IV Decision	0	0			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	N/A			

**Table 3.2 DRH - OIR - CDRH - PMA Real-Time Supplements Performance Metric - Rate of Not Approvable**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	2	0			
Number with MDUFA IV Decision	2	0			
Number of Not Approvable	0	0			
Rate of Not Approvable	0%	N/A			

**Table 3.3 DRH - OIR - CDRH - PMA Real-Time Supplements Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

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## **Section 4 Pre-Market Report Submissions**

There were no pre-market reports received by FDA between October 1, 2018 and March 31, 2019.

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## **Section 5 PMA Annual Metrics and Goals**

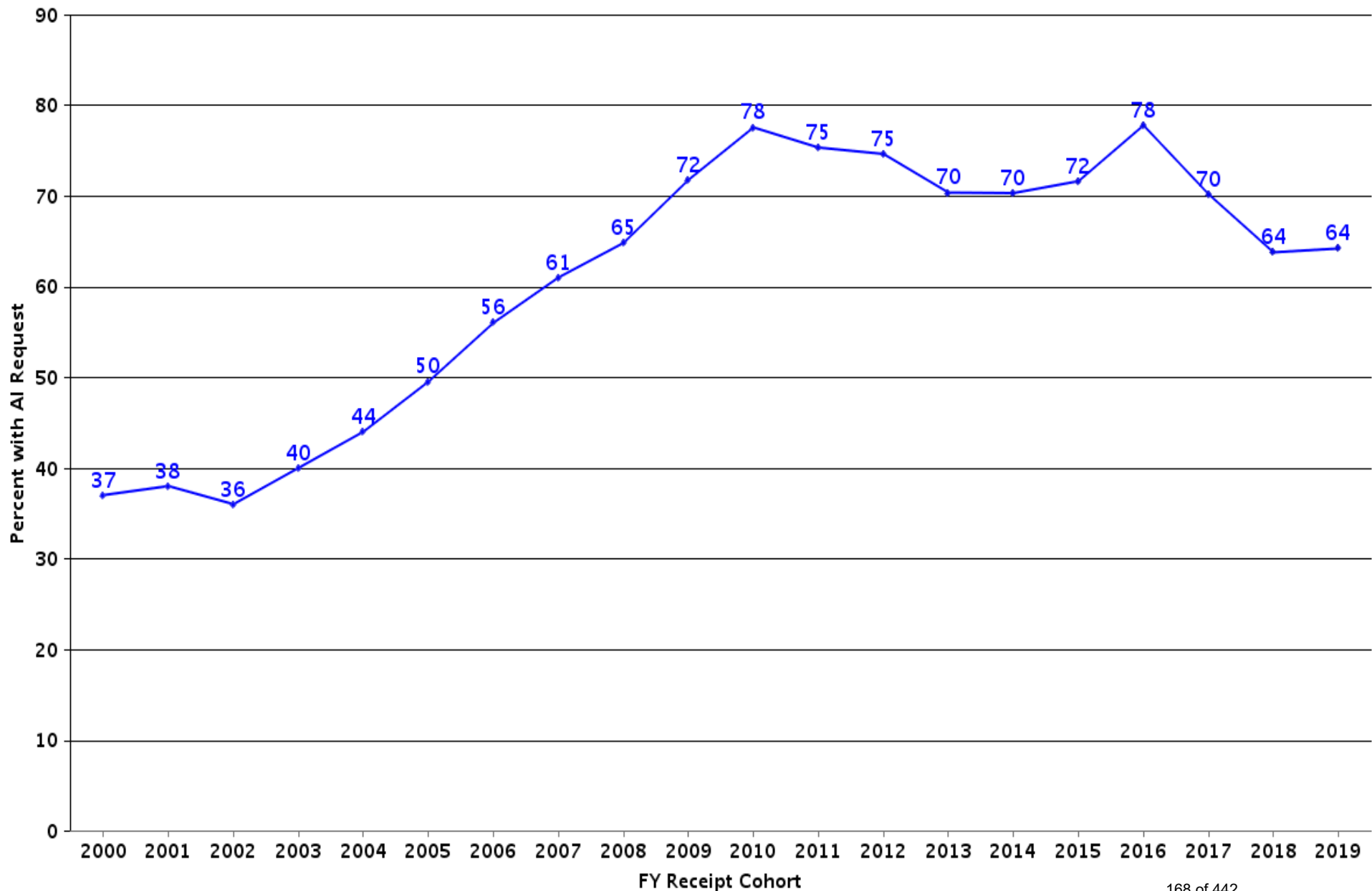
PMA Annual Metrics and Goals will be reported in the Annual Report.

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510(k)s

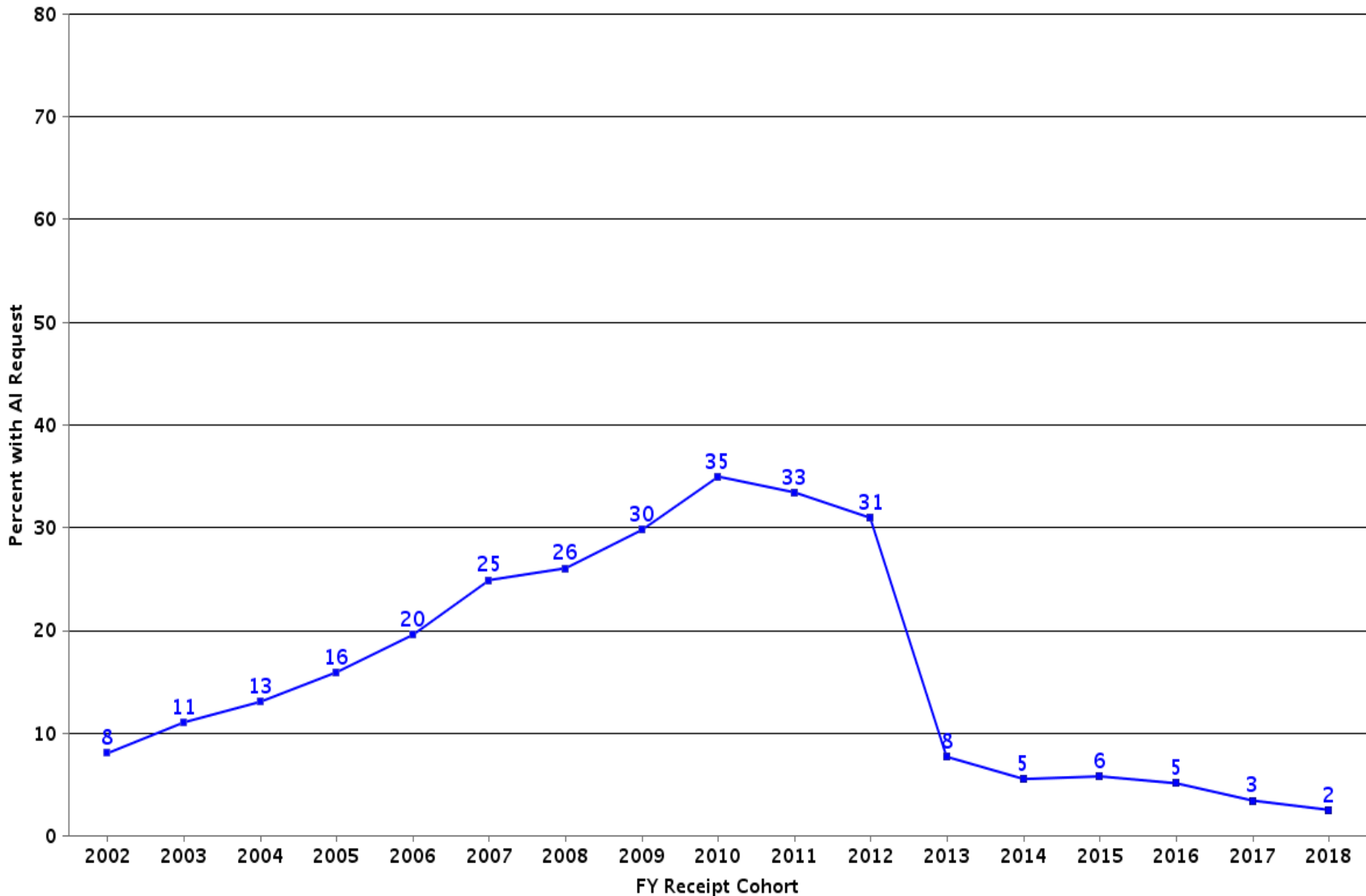
Q2FY19

# Percent of 510(k)s With Additional Information (AI) Request on 1st FDA Review Cycle





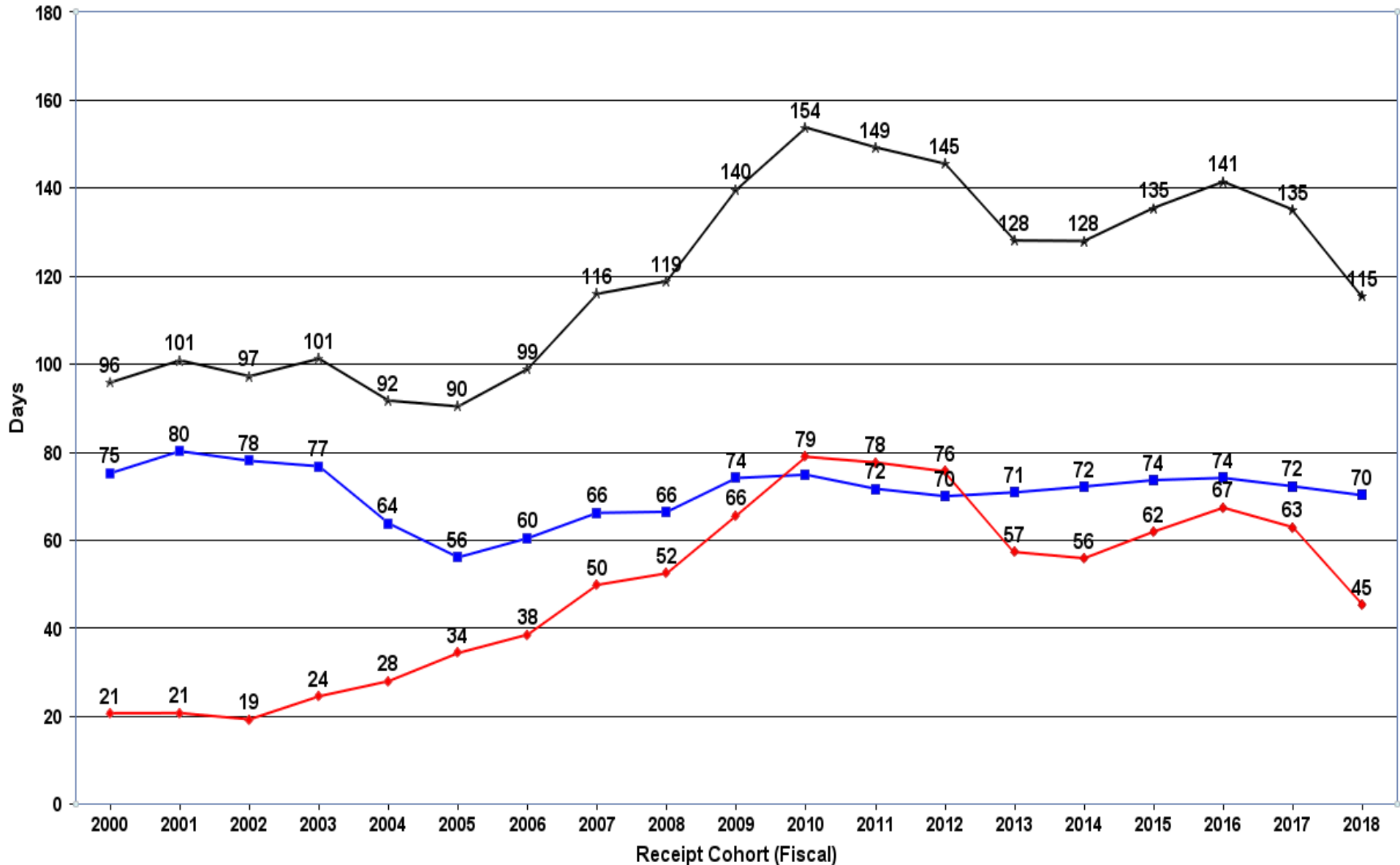
# Percent of 510(k)s With Additional Information (AI) Request on 2nd FDA Review Cycle



AI rates after FY13 are based on the 2nd substantive review cycle (i.e., excluding RTA cycles) for 510ks accepted as of 6/8/2018

■ % with 2nd Cycle AI Request

### 510(k) Average Days to MDUFA (SE/NSE) Decision as of: 3/31/19

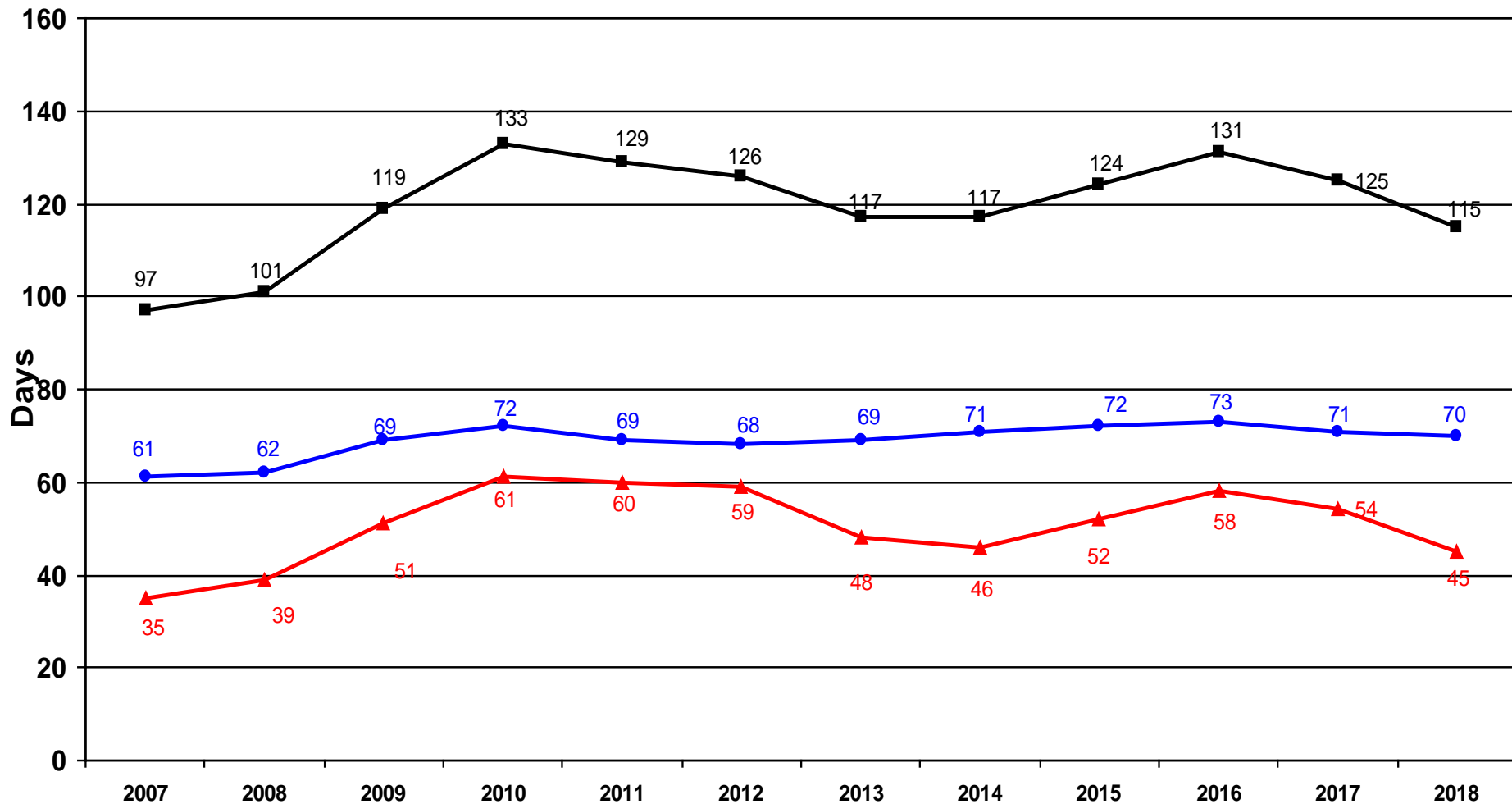


Cohorts not yet closed: 2017: 99.79%; 2018: 89.29%

170 of 442

■ Avg FDA Days to MDUFA Decision ♦ Avg Applicant Days to MDUFA Decision ★ Avg Total Elapsed Days to MDUFA Decision

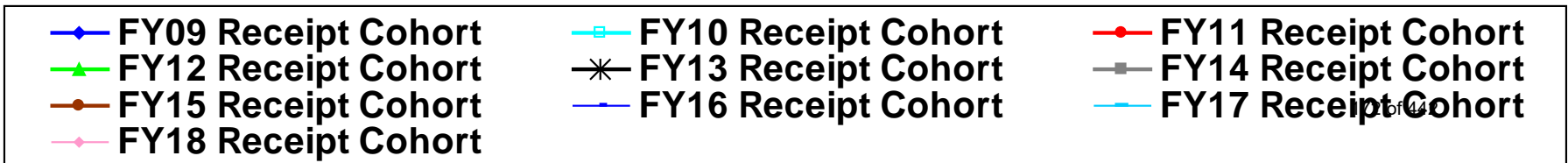
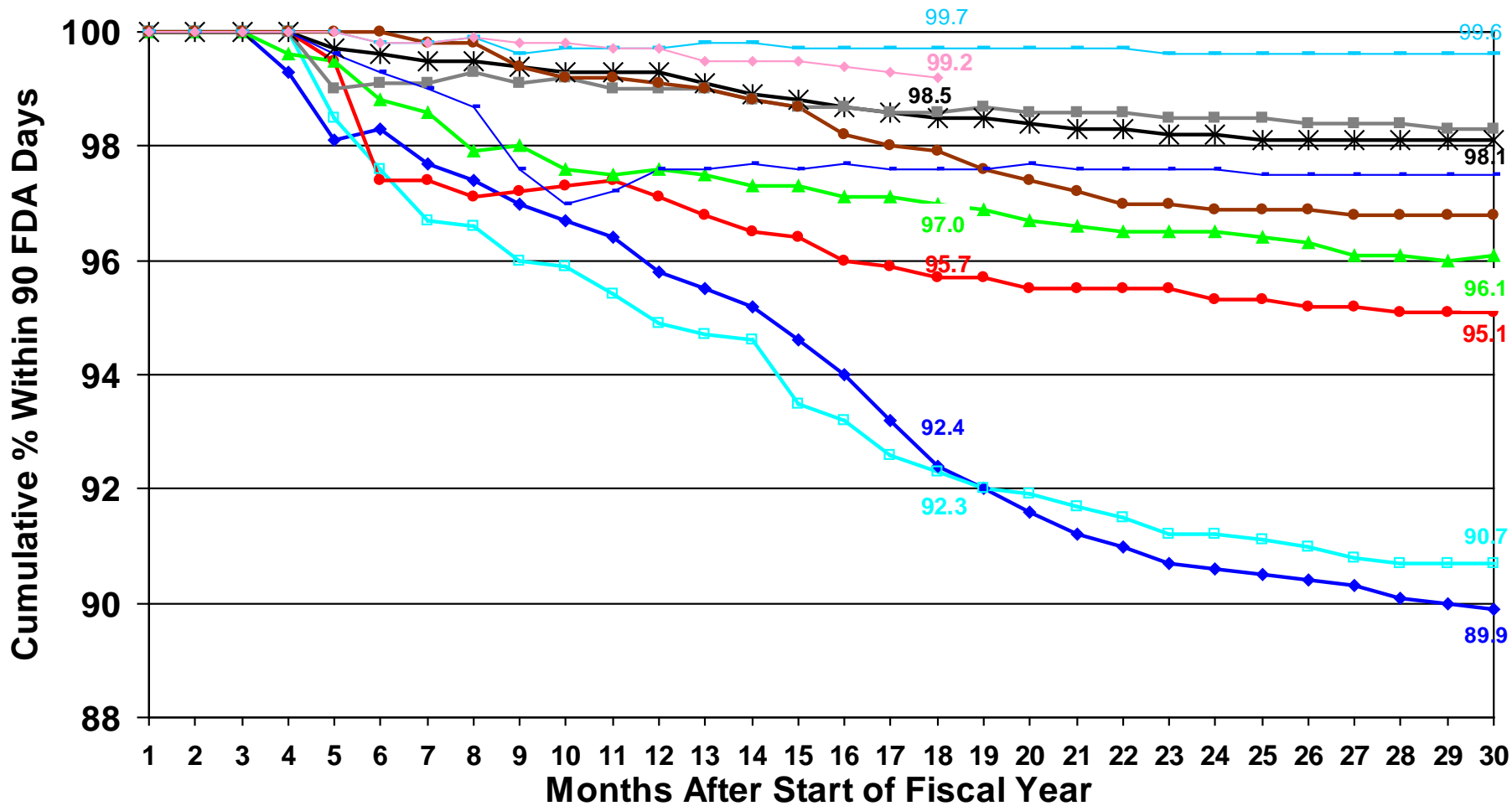
# 510(k) Average Days to MDUFA (SE/NSE) Decision Comparison of Receipt Cohorts at 89.3% Closure



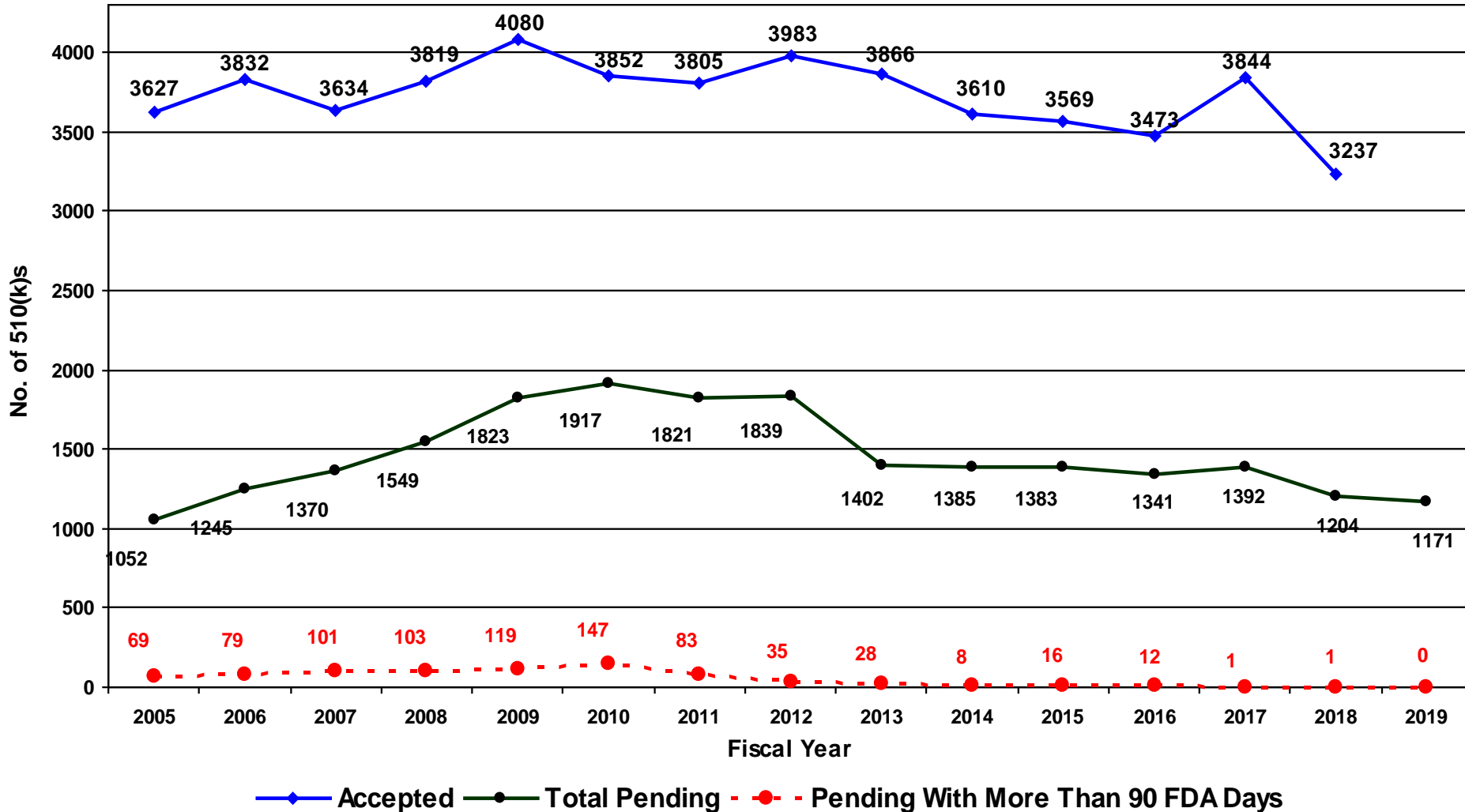
■ Avg Total Days to MDUFA Decision    ● Avg FDA Days to MDUFA Decision    ▲ Avg Applicant Days to MDUFA Decision

# Trend in 510(k) MDUFA Decision Goal Performance

## Comparison of FY09 - FY19 Receipt Cohorts

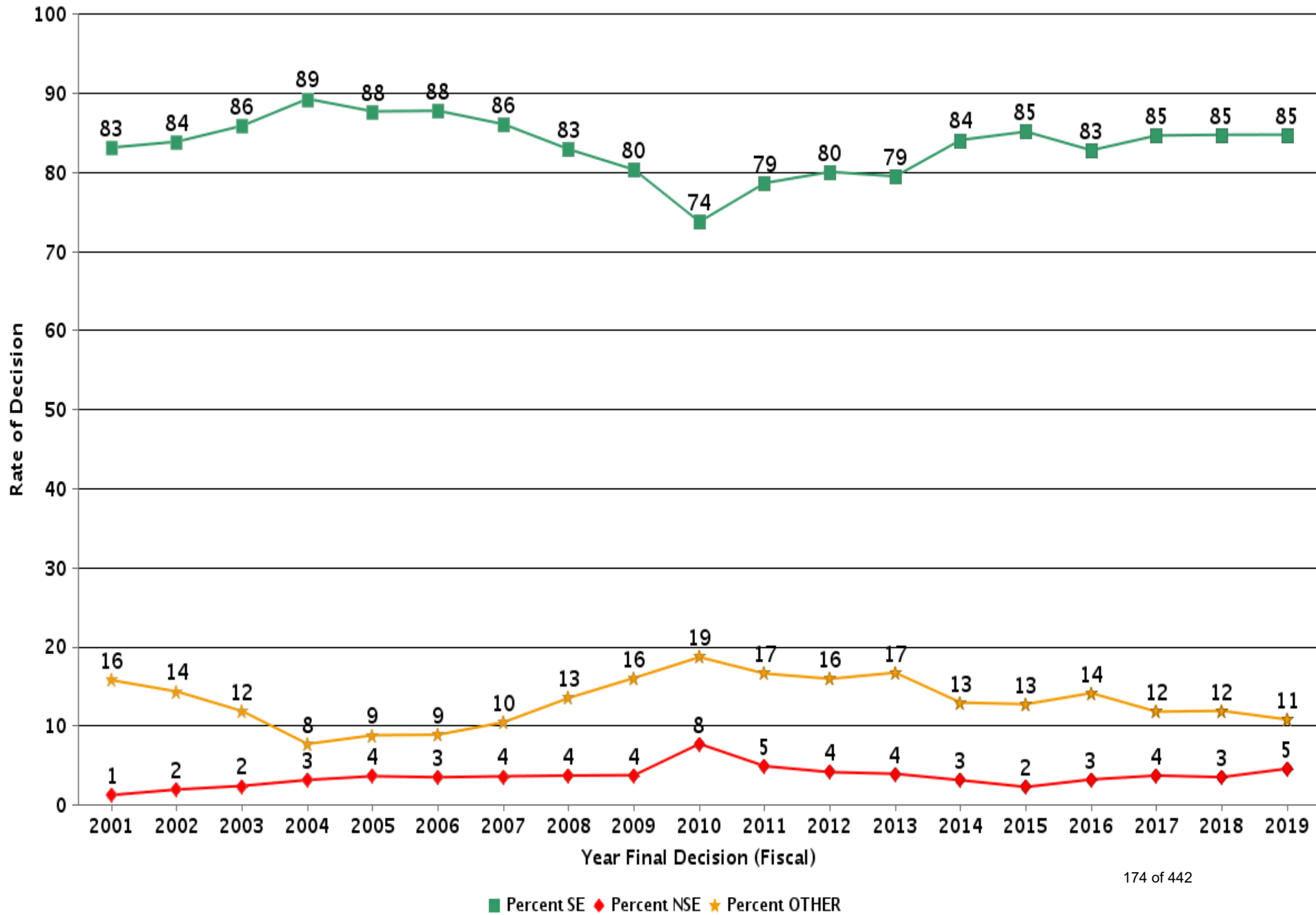


# 510(k)s Pending at End of Quarter/Year



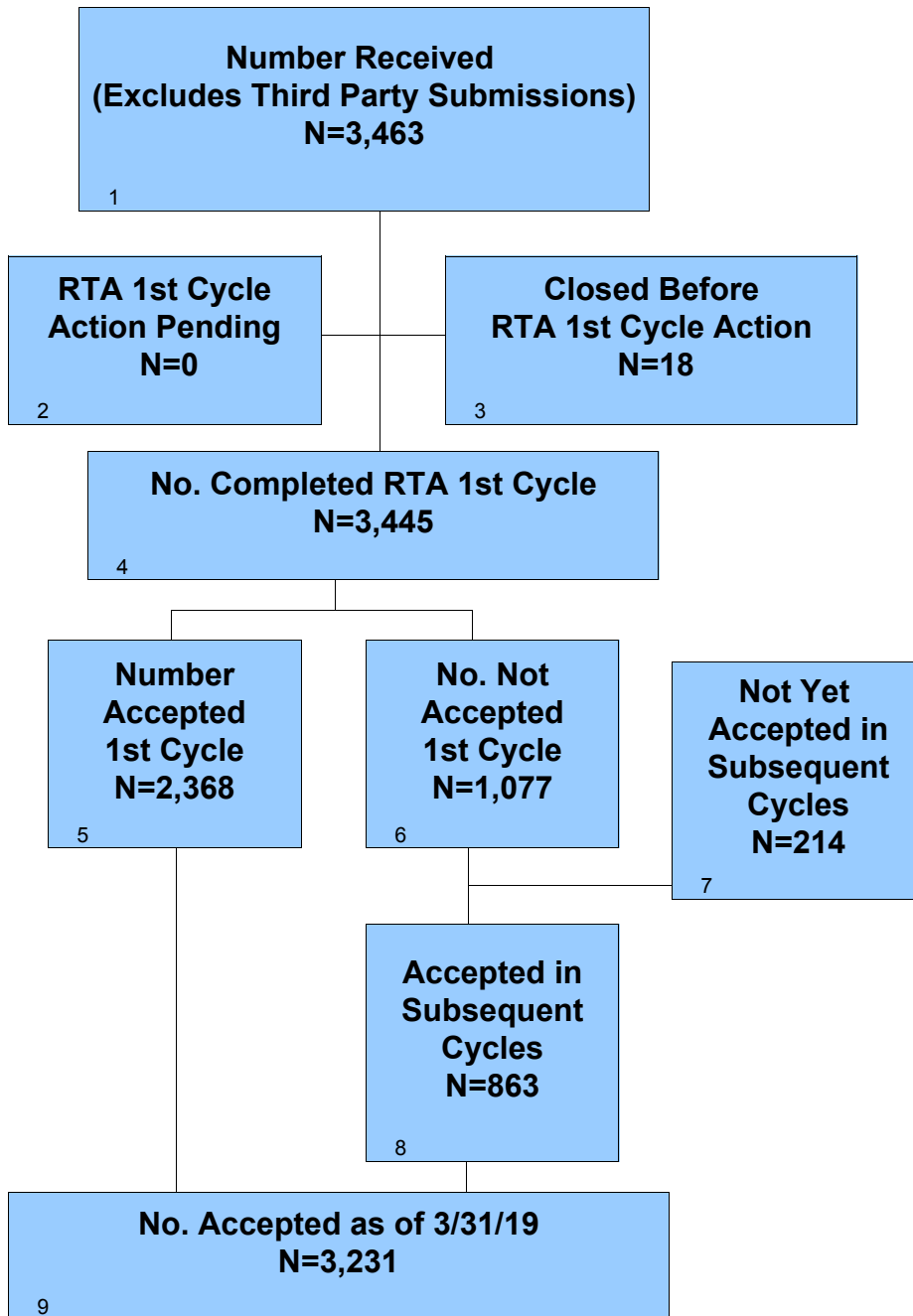
“Pending” means 510ks under review or on hold following a positive RTA decision (FY13 and later).

# Rates of SE, NSE and Other Decisions by FY of Decision

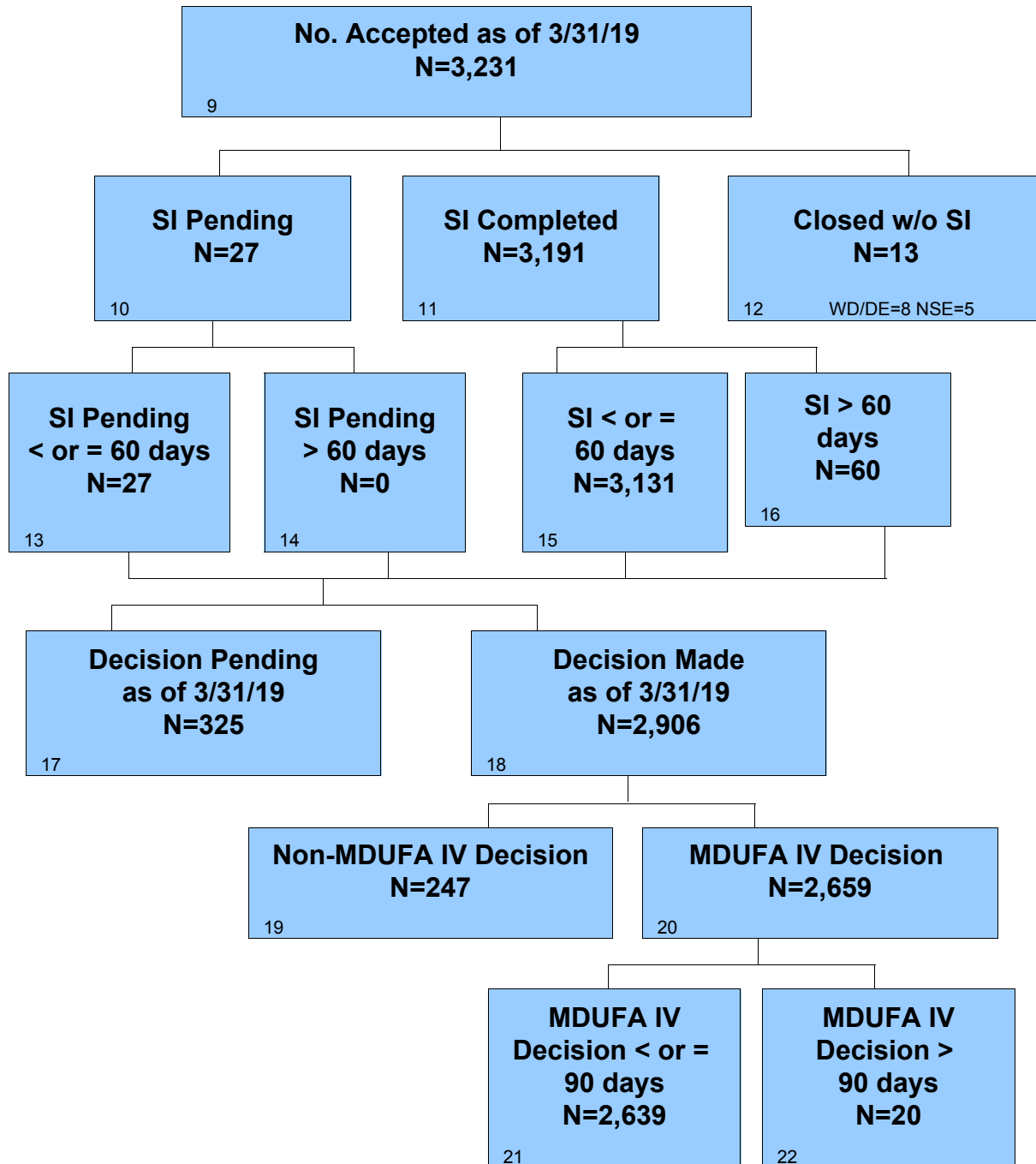


# CDRH 510(k)s - FY 2018 as of 3/31/19

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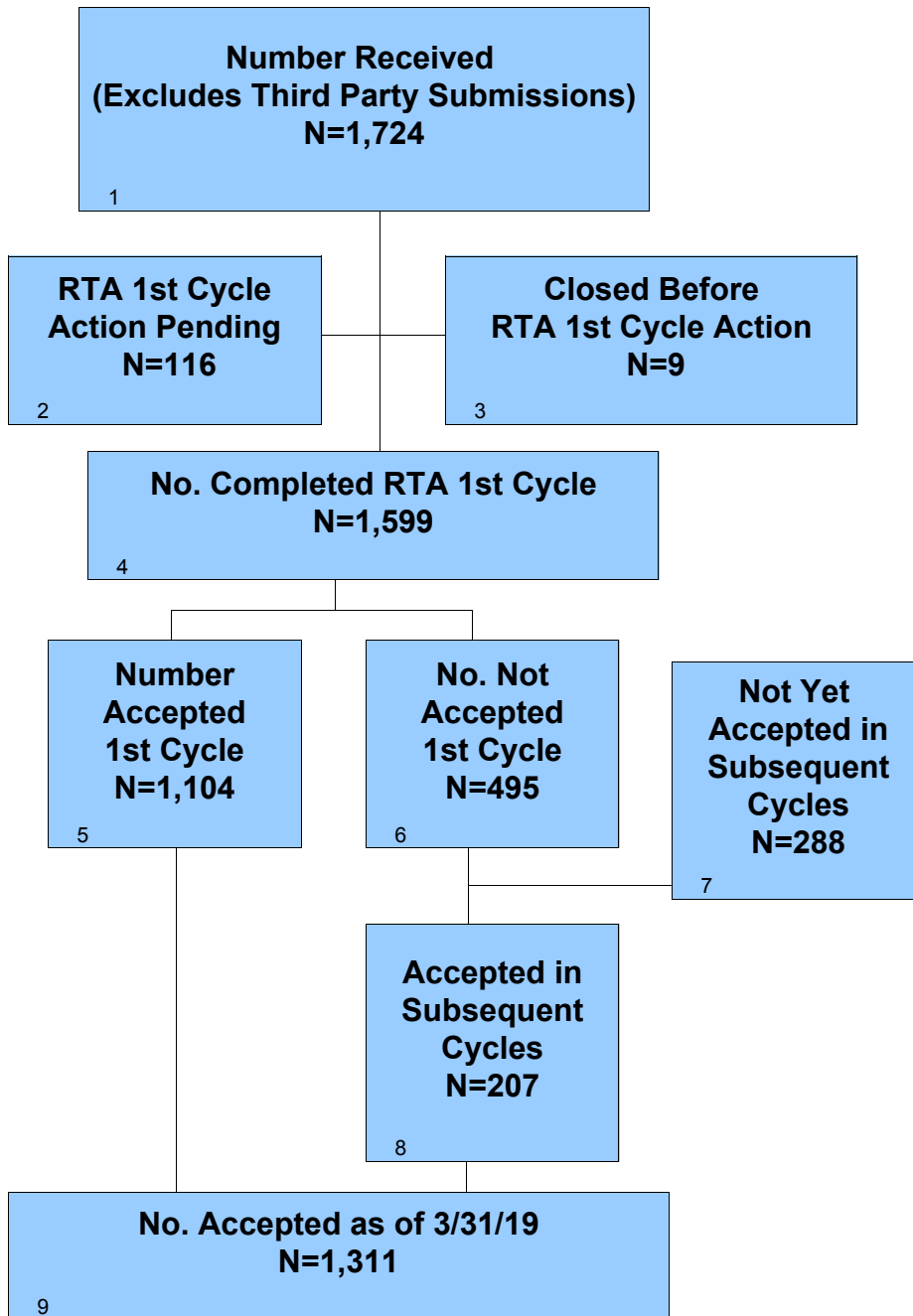
# CDRH 510(k)s - FY 2018 as of 3/31/19 Continued



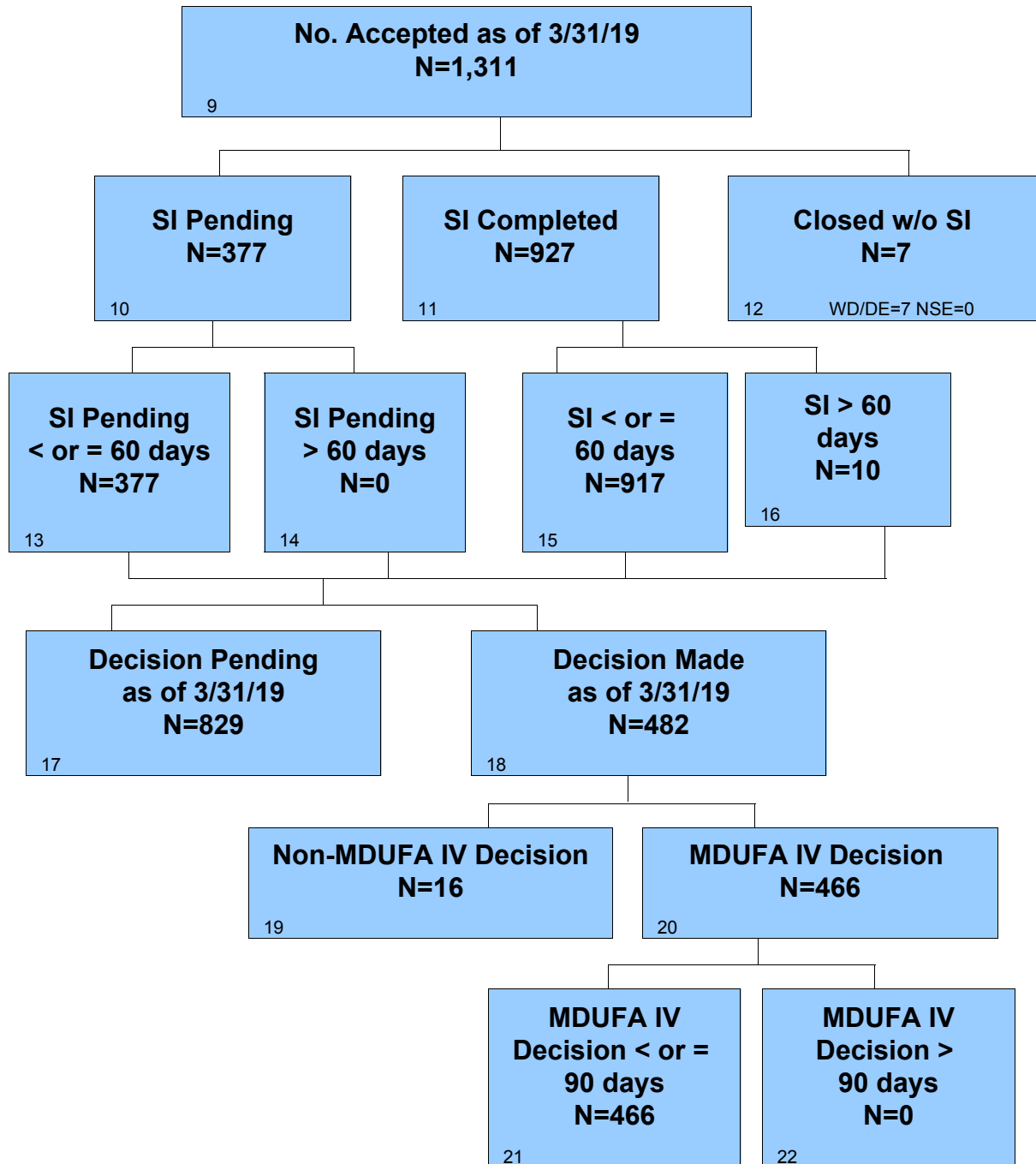


# CDRH 510(k)s - FY 2019 as of 3/31/19

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# CDRH 510(k)s - FY 2019 as of 3/31/19 Continued



## Section 6 510(k) Center Level Metrics (Excludes Third Party Review)

Table 6.1 CDRH - 510(k) Acceptance Review Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	3463	1724			
Closed Before RTA Action	18	9			
Number Accepted	2353	1076			
Number Without a RTA Review and > 15 Days Since Date Received	15	28			
Number Without a RTA Review and <= 15 Days Since Date Received	0	116			
Number Not Accepted	1077	495			
Rate of Submissions Not Accepted for Review	31.26%	30.96%			

Table 6.2 CDRH - 510(k) Substantive Interaction Performance Goal

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days
Eligible for SI	3231	1311			
Deleted or Withdrawn Prior to SI	8	7			
SI Within 60 FDA Days	3131	917			
SI Over 60 FDA Days	60	10			
SI Pending Within 60 FDA Days	27	377			
SI Pending Over 60 FDA Days	0	0			
510(k)s NSE Without SI	5	0			
Current SI Performance Percent Within 60 FDA Days	97.97%	98.92%			

**Table 6.3 CDRH - 510(k) Substantive Interaction Metric - Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number of Substantive Interaction	3191	927			
Average Number of FDA Days to Substantive Interaction	50.89	48.67			
20th Percentile FDA Days to Substantive Interaction	42	30			
40th Percentile FDA Days to Substantive Interaction	55	52			
60th Percentile FDA Days to Substantive Interaction	58	58			
80th Percentile FDA Days to Substantive Interaction	60	59			
Maximum FDA Days to Substantive Interaction	86	78			

**Table 6.4 CDRH - 510(k) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>		<b>FY 2019</b>		<b>FY 2020</b>		<b>FY 2021</b>		<b>FY 2022</b>	
	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>
510(k)s Accepted	3231	1311								
Non-MDUFA IV Decision	247	16								
MDUFA IV Decision (SE/NSE)	2659	466								
MDUFA IV Decision Within 90 FDA Days	2639	466								
510(k)s Pending MDUFA IV Decision	325	829								
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0								
Current Performance Percent Within 90 FDA Days	99.25%	100%								

**Table 6.5 CDRH - 510(k) Time to MDUFA IV Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Average Review Cycles	1.59	1.30			
Number With MDUFA IV Decision	2659	466			
<b>Average Number of FDA Days to MDUFA IV Decision</b>	<b>71.13</b>	<b>56.08</b>			
20th Percentile FDA Days to MDUFA IV Decision	51	29			
40th Percentile FDA Days to MDUFA IV Decision	77	49			
60th Percentile FDA Days to MDUFA IV Decision	87	63			
80th Percentile FDA Days to MDUFA IV Decision	89	86			
Maximum FDA Days to MDUFA IV Decision	170	90			
<b>Average Number of Industry Days to MDUFA IV Decision</b>	<b>45.68</b>	<b>8.90</b>			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	34	0			
80th Percentile Industry Days to MDUFA IV Decision	96	17			
Maximum Industry Days to MDUFA IV Decision	316	115			
<b>Average Number of Total Days to MDUFA IV Decision</b>	<b>116.81</b>	<b>64.98</b>			
20th Percentile Total Days to MDUFA IV Decision	56	29			
40th Percentile Total Days to MDUFA IV Decision	87	50			
60th Percentile Total Days to MDUFA IV Decision	117	77			
80th Percentile Total Days to MDUFA IV Decision	181	94			
Maximum Total Days to MDUFA IV Decision	400	174			

**Table 6.6 CDRH - 510(k) Performance Metric - Rates of SE, NSE, Withdrawal, and Delete Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
510(k) Accepted	3231	1311			
Number With MDUFA IV Decision	2659	466			
Number of SE Decision	2562	462			
Number of NSE Decision	97	4			
Number of Withdrawal	141	13			
Number of Deleted	98	0			
Rate of SE Decision	96.35%	99.14%			
Rate of NSE Decision	3.65%	0.86%			
Rate of Withdrawal	4.36%	0.99%			
Rate of Deleted	3.03%	0%			

**Table 6.7 CDRH - 510(k) Performance Metric - Submissions Missing Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number of Submissions that Missed the Goal	20	0			
Mean FDA Days for Submissions that Missed the Goal	107.35	0			
Mean Industry Days for Submissions that Missed the Goal	95	0			

**Table 6.8 CDRH - LDT 510(k) MDUFA IV Decision Metric**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	2	1			
Non-MDUFA IV Decision	1	0			
MDUFA IV Decision (SE/NSE)	1	0			
MDUFA IV Decision Within 90 FDA Days	1	0			
510(k)s Pending MDUFA IV Decision	0	1			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	100%	N/A			

**Table 6.9 CDRH - Conventional IVD (Non-LDT) 510(k) MDUFA IV Decision Metric**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	271	123			
Non-MDUFA IV Decision	32	1			
MDUFA IV Decision (SE/NSE)	214	53			
MDUFA IV Decision Within 90 FDA Days	213	53			
510(k)s Pending MDUFA IV Decision	25	69			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	100%	100%			

## Section 6 510(k) Office Level Metric (Excludes Third Party Review)

**Table 6.1 ODE - CDRH - 510(k) Acceptance Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	2783	1386			
Closed Before RTA Action	15	7			
Number Accepted	1761	819			
Number Without a RTA and > 15 Days Since Date Received	13	22			
Number Without a RTA and <= 15 Days Since Date Received	0	100			
Number Not Accepted	994	438			
Rate of Submissions Not Accepted For Review	35.91%	34.25%			

**Table 6.2 ODE - CDRH - 510(k) Substantive Interaction (SI) Performance Goal**

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days
Eligible For SI	2573	1024			
Deleted or Withdrawn Prior to SI	6	6			
SI Within 60 FDA Days	2479	696			
SI Over 60 FDA Days	59	10			
SI Pending Within 60 FDA Days	25	312			
SI Pending Over 60 FDA Days	0	0			
510(k)s NSE Without SI	4	0			
Current SI Performance Percent Within 60 FDA Days	97.52%	98.58%			



**Table 6.3 ODE - CDRH - 510(k) Substantive Interaction Metric - Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number of Substantive Interaction	2538	706			
Average Number of FDA Days to Substantive Interaction	52.02	49.40			
20th Percentile FDA Days to Substantive Interaction	47	30			
40th Percentile FDA Days to Substantive Interaction	56	54			
60th Percentile FDA Days to Substantive Interaction	58	58			
80th Percentile FDA Days to Substantive Interaction	60	60			
Maximum FDA Days to Substantive Interaction	86	78			

**Table 6.4 ODE - CDRH - 510(k) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>
510(k)s Accepted	2573	1024			
Non-MDUFA IV Decision	203	13			
MDUFA IV Decision (SE/NSE)	2083	325			
MDUFA IV Decision Within 90 FDA Days	2064	325			
510(k)s Pending MDUFA IV Decision	287	686			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	99.09%	100%			

Table 6.5 ODE - CDRH - 510(k) Time to MDUFA IV Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.62	1.35			
Number With MDUFA IV Decision	2083	325			
<b>Average Number of FDA Days to MDUFA IV Decision</b>	73.30	57.50			
20th Percentile FDA Days to MDUFA IV Decision	56	29			
40th Percentile FDA Days to MDUFA IV Decision	80	49			
60th Percentile FDA Days to MDUFA IV Decision	87	68			
80th Percentile FDA Days to MDUFA IV Decision	89	87			
Maximum FDA Days to MDUFA IV Decision	170	90			
<b>Average Number of Industry Days to MDUFA IV Decision</b>	47.93	9.96			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	4	0			
60th Percentile Industry Days to MDUFA IV Decision	38	0			
80th Percentile Industry Days to MDUFA IV Decision	102	20			
Maximum Industry Days to MDUFA IV Decision	316	115			
<b>Average Number of Total Days to MDUFA IV Decision</b>	121.23	67.45			
20th Percentile Total Days to MDUFA IV Decision	58	29			
40th Percentile Total Days to MDUFA IV Decision	89	53			
60th Percentile Total Days to MDUFA IV Decision	122	84			
80th Percentile Total Days to MDUFA IV Decision	188	98			
Maximum Total Days to MDUFA IV Decision	400	174			

**Table 6.6 ODE - CDRH - 510(k) Performance Metric - Rates of SE, NSE, Withdrawal, and Delete Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
510(k) Accepted	2573	1024			
Number With MDUFA IV Decision	2083	325			
Number of SE Decision	2003	321			
Number of NSE Decision	80	4			
Number of Withdrawal	116	10			
Number of Deleted	81	0			
Rate of SE Decision	96.16%	98.77%			
Rate of NSE Decision	3.84%	1.23%			
Rate of Withdrawal	4.51%	0.98%			
Rate of Deleted	3.15%	0%			

**Table 6.7 ODE - CDRH - 510(k) Performance Metric - Submission Missing Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number of Submissions that Missed the Goal	19	0			
Mean FDA Days for Submissions that Missed the Goal	108.11	0			
Mean Industry Days for Submissions that Missed the Goal	89.47	0			

**Table 6.8 ODE - CDRH - LDT 510(k) MDUFA IV Decision Metric**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	0	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision (SE/NSE)	0	0			
MDUFA IV Decision Within 90 FDA Days	0	0			
510(k)s Pending MDUFA IV Decision	0	0			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	N/A	N/A			

**Table 6.9 ODE - CDRH - Conventional IVD (Non-LDT) 510(k) MDUFA IV Decision Metric**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	0	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision (SE/NSE)	0	0			
MDUFA IV Decision Within 90 FDA Days	0	0			
510(k)s Pending MDUFA IV Decision	0	0			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	N/A	N/A			

## Section 6 510(k) Office Level Metric (Excludes Third Party Review)

**Table 6.1 OIR - CDRH - 510(k) Acceptance Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	680	338			
Closed Before RTA Action	3	2			
Number Accepted	592	257			
Number Without a RTA and > 15 Days Since Date Received	2	6			
Number Without a RTA and <= 15 Days Since Date Received	0	16			
Number Not Accepted	83	57			
Rate of Submissions Not Accepted For Review	12.26%	17.81%			

**Table 6.2 OIR - CDRH - 510(k) Substantive Interaction (SI) Performance Goal**

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days
Eligible For SI	658	287			
Deleted or Withdrawn Prior to SI	2	1			
SI Within 60 FDA Days	652	221			
SI Over 60 FDA Days	1	0			
SI Pending Within 60 FDA Days	2	65			
SI Pending Over 60 FDA Days	0	0			
510(k)s NSE Without SI	1	0			
Current SI Performance Percent Within 60 FDA Days	99.69%	100%			

**Table 6.3 OIR - CDRH - 510(k) Substantive Interaction Metric - Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number of Substantive Interaction	653	221			
Average Number of FDA Days to Substantive Interaction	46.49	46.35			
20th Percentile FDA Days to Substantive Interaction	30	30			
40th Percentile FDA Days to Substantive Interaction	48	49			
60th Percentile FDA Days to Substantive Interaction	56	55			
80th Percentile FDA Days to Substantive Interaction	58	58			
Maximum FDA Days to Substantive Interaction	61	60			

**Table 6.4 OIR - CDRH - 510(k) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>
510(k)s Accepted	658	287			
Non-MDUFA IV Decision	44	3			
MDUFA IV Decision (SE/NSE)	576	141			
MDUFA IV Decision Within 90 FDA Days	575	141			
510(k)s Pending MDUFA IV Decision	38	143			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	99.83%	100%			

Table 6.5 OIR - CDRH - 510(k) Time to MDUFA IV Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.48	1.19			
Number With MDUFA IV Decision	576	141			
<b>Average Number of FDA Days to MDUFA IV Decision</b>	63.30	52.82			
20th Percentile FDA Days to MDUFA IV Decision	30	28			
40th Percentile FDA Days to MDUFA IV Decision	59	46			
60th Percentile FDA Days to MDUFA IV Decision	80	59			
80th Percentile FDA Days to MDUFA IV Decision	88	83			
Maximum FDA Days to MDUFA IV Decision	93	90			
<b>Average Number of Industry Days to MDUFA IV Decision</b>	37.56	6.47			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	19	0			
80th Percentile Industry Days to MDUFA IV Decision	78	0			
Maximum Industry Days to MDUFA IV Decision	231	83			
<b>Average Number of Total Days to MDUFA IV Decision</b>	100.86	59.28			
20th Percentile Total Days to MDUFA IV Decision	30	28			
40th Percentile Total Days to MDUFA IV Decision	66	48			
60th Percentile Total Days to MDUFA IV Decision	93	64			
80th Percentile Total Days to MDUFA IV Decision	157	90			
Maximum Total Days to MDUFA IV Decision	321	169			

**Table 6.6 OIR - CDRH - 510(k) Performance Metric - Rates of SE, NSE, Withdrawal, and Delete Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
510(k) Accepted	658	287			
Number With MDUFA IV Decision	576	141			
Number of SE Decision	559	141			
Number of NSE Decision	17	0			
Number of Withdrawal	25	3			
Number of Deleted	17	0			
Rate of SE Decision	97.05%	100%			
Rate of NSE Decision	2.95%	0%			
Rate of Withdrawal	3.80%	1.05%			
Rate of Deleted	2.58%	0%			

**Table 6.7 OIR - CDRH - 510(k) Performance Metric - Submission Missing Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number of Submissions that Missed the Goal	1	0			
Mean FDA Days for Submissions that Missed the Goal	93.00	0			
Mean Industry Days for Submissions that Missed the Goal	202	0			



**Table 6.8 OIR - CDRH - LDT 510(k) MDUFA IV Decision Metric**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	2	1			
Non-MDUFA IV Decision	1	0			
MDUFA IV Decision (SE/NSE)	1	0			
MDUFA IV Decision Within 90 FDA Days	1	0			
510(k)s Pending MDUFA IV Decision	0	1			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	100%	N/A			

**Table 6.9 OIR - CDRH - Conventional IVD (Non-LDT) 510(k) MDUFA IV Decision Metric**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	271	123			
Non-MDUFA IV Decision	32	1			
MDUFA IV Decision (SE/NSE)	214	53			
MDUFA IV Decision Within 90 FDA Days	213	53			
510(k)s Pending MDUFA IV Decision	25	69			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	100%	100%			

## Section 6 510(k) Division Level Metric (Excludes Third Party Review)

Table 6.1 DAGRID - ODE - CDRH - 510(k) Acceptance Review Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	695	334			
Closed Before RTA Action	3	0			
Number Accepted	262	112			
Number Without a RTA and > 15 Days Since Date Received	3	3			
Number Without a RTA and <= 15 Days Since Date Received	0	29			
Number Not Accepted	427	190			
Rate of Submissions Not Accepted for Review	61.71%	62.30%			

Table 6.2 DAGRID - ODE - CDRH - 510(k) Substantive Interaction Performance Goal

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days
Eligible For SI	594	187			
Deleted or Withdrawn Prior to SI	0	2			
SI Within 60 FDA Days	566	114			
SI Over 60 FDA Days	16	5			
SI Pending Within 60 FDA Days	12	66			
SI Pending Over 60 FDA Days	0	0			
510(k)s NSE Without SI	0	0			
Current SI Performance Percent Within 60 FDA Days	97.25%	95.80%			

**Table 6.3 DAGRID - ODE - CDRH - 510(k) Substantive Interaction Metric - Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number of Substantive Interactions	582	119			
Average Number of FDA Days to Substantive Interaction	55.41	52.90			
20th Percentile FDA Days to Substantive Interaction	54	49			
40th Percentile FDA Days to Substantive Interaction	57	56			
60th Percentile FDA Days to Substantive Interaction	59	58			
80th Percentile FDA Days to Substantive Interaction	60	60			
Maximum FDA Days to Substantive Interaction	78	78			

**Table 6.4 DAGRID - ODE - CDRH - 510(k) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>
510(k)s Accepted	594	187			
Non-MDUFA IV Decision	53	2			
MDUFA IV Decision (SE/NSE)	427	42			
MDUFA IV Decision Within 90 FDA Days	422	42			
510(k)s Pending MDUFA IV Decision	114	143			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	98.83%	100%			

Table 6.5 DAGRID - ODE - CDRH - 510(k) Time to MDUFA IV Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.74	1.45			
Number With MDUFA IV Decision	427	42			
<b>Average Number of FDA Days to MDUFA IV Decision</b>	81.74	67.05			
20th Percentile FDA Days to MDUFA IV Decision	78	37			
40th Percentile FDA Days to MDUFA IV Decision	86	73			
60th Percentile FDA Days to MDUFA IV Decision	88	84			
80th Percentile FDA Days to MDUFA IV Decision	90	87			
Maximum FDA Days to MDUFA IV Decision	118	90			
<b>Average Number of Industry Days to MDUFA IV Decision</b>	61.60	14.86			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	25	0			
60th Percentile Industry Days to MDUFA IV Decision	58	7			
80th Percentile Industry Days to MDUFA IV Decision	129	32			
Maximum Industry Days to MDUFA IV Decision	214	69			
<b>Average Number of Total Days to MDUFA IV Decision</b>	143.33	81.90			
20th Percentile Total Days to MDUFA IV Decision	85	37			
40th Percentile Total Days to MDUFA IV Decision	109	79			
60th Percentile Total Days to MDUFA IV Decision	144	89			
80th Percentile Total Days to MDUFA IV Decision	213	118			
Maximum Total Days to MDUFA IV Decision	304	158			

**Table 6.6 DAGRID - ODE - CDRH - 510(k) Performance Metric - Rates of SE, NSE, Withdrawal, and Delete Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
510(k) Accepted	594	187			
Number With MDUFA IV Decision	427	42			
Number of SE Decision	407	42			
Number of NSE Decision	20	0			
Number of Withdrawal	30	2			
Number of Deleted	23	0			
Rate of SE Decision	95.32%	100%			
Rate of NSE Decision	4.68%	0%			
Rate of Withdrawal	5.05%	1.07%			
Rate of Deleted	3.87%	0%			

**Table 6.7 DAGRID - ODE - CDRH - 510(k) Performance Metric - Submissions Missing Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number of Submissions that Missed the Goal	5	0			
Mean FDA Days for Submissions that Missed the Goal	101.2	0			
Mean Industry Days for Submissions that Missed the Goal	112	0			

**Table 6.8 DAGRID - ODE - CDRH - LDT 510(k) MDUFA IV Decision Metric**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	0	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision (SE/NSE)	0	0			
MDUFA IV Decision Within 90 FDA Days	0	0			
510(k)s Pending MDUFA IV Decision	0	0			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	N/A	N/A			

**Table 6.9 DAGRID - ODE - CDRH - Conventional IVD (Non-LDT) 510(k) MDUFA IV Decision Metric**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	0	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision (SE/NSE)	0	0			
MDUFA IV Decision Within 90 FDA Days	0	0			
510(k)s Pending MDUFA IV Decision	0	0			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	N/A	N/A			

## Section 6 510(k) Division Level Metric (Excludes Third Party Review)

Table 6.1 DCD - ODE - CDRH - 510(k) Acceptance Review Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	357	192			
Closed Before RTA Action	4	1			
Number Accepted	237	123			
Number Without a RTA and > 15 Days Since Date Received	2	5			
Number Without a RTA and <= 15 Days Since Date Received	0	10			
Number Not Accepted	114	53			
Rate of Submissions Not Accepted for Review	32.29%	29.28%			

Table 6.2 DCD - ODE - CDRH - 510(k) Substantive Interaction Performance Goal

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days
Eligible For SI	338	157			
Deleted or Withdrawn Prior to SI	4	0			
SI Within 60 FDA Days	320	109			
SI Over 60 FDA Days	13	4			
SI Pending Within 60 FDA Days	1	44			
SI Pending Over 60 FDA Days	0	0			
510(k)s NSE Without SI	0	0			
Current SI Performance Percent Within 60 FDA Days	96.10%	96.46%			

**Table 6.3 DCD - ODE - CDRH - 510(k) Substantive Interaction Metric - Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number of Substantive Interactions	333	113			
Average Number of FDA Days to Substantive Interaction	49.64	48.77			
20th Percentile FDA Days to Substantive Interaction	30	29			
40th Percentile FDA Days to Substantive Interaction	53	55			
60th Percentile FDA Days to Substantive Interaction	58	58			
80th Percentile FDA Days to Substantive Interaction	60	60			
Maximum FDA Days to Substantive Interaction	83	69			

**Table 6.4 DCD - ODE - CDRH - 510(k) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>
510(k)s Accepted	338	157			
Non-MDUFA IV Decision	22	2			
MDUFA IV Decision (SE/NSE)	281	45			
MDUFA IV Decision Within 90 FDA Days	277	45			
510(k)s Pending MDUFA IV Decision	35	110			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	98.58%	100%			



Table 6.5 DCD - ODE - CDRH - 510(k) Time to MDUFA IV Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.68	1.36			
Number With MDUFA IV Decision	281	45			
<b>Average Number of FDA Days to MDUFA IV Decision</b>	70.14	51.11			
20th Percentile FDA Days to MDUFA IV Decision	47	27			
40th Percentile FDA Days to MDUFA IV Decision	77	30			
60th Percentile FDA Days to MDUFA IV Decision	87	59			
80th Percentile FDA Days to MDUFA IV Decision	90	85			
Maximum FDA Days to MDUFA IV Decision	159	90			
<b>Average Number of Industry Days to MDUFA IV Decision</b>	56.54	12.33			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	15	0			
60th Percentile Industry Days to MDUFA IV Decision	46	0			
80th Percentile Industry Days to MDUFA IV Decision	115	23			
Maximum Industry Days to MDUFA IV Decision	292	115			
<b>Average Number of Total Days to MDUFA IV Decision</b>	126.69	63.44			
20th Percentile Total Days to MDUFA IV Decision	51	28			
40th Percentile Total Days to MDUFA IV Decision	92	30			
60th Percentile Total Days to MDUFA IV Decision	130	60			
80th Percentile Total Days to MDUFA IV Decision	203	100			
Maximum Total Days to MDUFA IV Decision	370	174			

**Table 6.6 DCD - ODE - CDRH - 510(k) Performance Metric - Rates of SE, NSE, Withdrawal, and Delete Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
510(k) Accepted	338	157			
Number With MDUFA IV Decision	281	45			
Number of SE Decision	267	44			
Number of NSE Decision	14	1			
Number of Withdrawal	13	1			
Number of Deleted	7	0			
Rate of SE Decision	95.02%	97.78%			
Rate of NSE Decision	4.98%	2.22%			
Rate of Withdrawal	3.85%	0.64%			
Rate of Deleted	2.07%	0%			

**Table 6.7 DCD - ODE - CDRH - 510(k) Performance Metric - Submissions Missing Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number of Submissions that Missed the Goal	4	0			
Mean FDA Days for Submissions that Missed the Goal	112.75	0			
Mean Industry Days for Submissions that Missed the Goal	115	0			

**Table 6.8 DCD - ODE - CDRH - LDT 510(k) MDUFA IV Decision Metric**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	0	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision (SE/NSE)	0	0			
MDUFA IV Decision Within 90 FDA Days	0	0			
510(k)s Pending MDUFA IV Decision	0	0			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	N/A	N/A			

**Table 6.9 DCD - ODE - CDRH - Conventional IVD (Non-LDT) 510(k) MDUFA IV Decision Metric**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	0	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision (SE/NSE)	0	0			
MDUFA IV Decision Within 90 FDA Days	0	0			
510(k)s Pending MDUFA IV Decision	0	0			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	N/A	N/A			

## Section 6 510(k) Division Level Metric (Excludes Third Party Review)

Table 6.1 DNPMD - ODE - CDRH - 510(k) Acceptance Review Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	259	130			
Closed Before RTA Action	3	0			
Number Accepted	146	70			
Number Without a RTA and > 15 Days Since Date Received	3	4			
Number Without a RTA and <= 15 Days Since Date Received	0	14			
Number Not Accepted	107	42			
Rate of Submissions Not Accepted for Review	41.80%	36.21%			

Table 6.2 DNPMD - ODE - CDRH - 510(k) Substantive Interaction Performance Goal

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days
Eligible For SI	227	97			
Deleted or Withdrawn Prior to SI	0	0			
SI Within 60 FDA Days	221	65			
SI Over 60 FDA Days	4	0			
SI Pending Within 60 FDA Days	2	32			
SI Pending Over 60 FDA Days	0	0			
510(k)s NSE Without SI	0	0			
Current SI Performance Percent Within 60 FDA Days	98.22%	100%			

**Table 6.3 DNPMD - ODE - CDRH - 510(k) Substantive Interaction Metric - Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number of Substantive Interactions	225	65			
Average Number of FDA Days to Substantive Interaction	53.83	52.02			
20th Percentile FDA Days to Substantive Interaction	53	30			
40th Percentile FDA Days to Substantive Interaction	58	58			
60th Percentile FDA Days to Substantive Interaction	60	59			
80th Percentile FDA Days to Substantive Interaction	60	60			
Maximum FDA Days to Substantive Interaction	86	60			

**Table 6.4 DNPMD - ODE - CDRH - 510(k) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>
510(k)s Accepted	227	97			
Non-MDUFA IV Decision	18	2			
MDUFA IV Decision (SE/NSE)	178	31			
MDUFA IV Decision Within 90 FDA Days	173	31			
510(k)s Pending MDUFA IV Decision	31	64			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	97.19%	100%			

Table 6.5 DNPMD - ODE - CDRH - 510(k) Time to MDUFA IV Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.48	1.32			
Number With MDUFA IV Decision	178	31			
<b>Average Number of FDA Days to MDUFA IV Decision</b>	75.20	64.77			
20th Percentile FDA Days to MDUFA IV Decision	58	30			
40th Percentile FDA Days to MDUFA IV Decision	84	60			
60th Percentile FDA Days to MDUFA IV Decision	89	86			
80th Percentile FDA Days to MDUFA IV Decision	90	90			
Maximum FDA Days to MDUFA IV Decision	170	90			
<b>Average Number of Industry Days to MDUFA IV Decision</b>	31.12	10.10			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	21	0			
80th Percentile Industry Days to MDUFA IV Decision	58	22			
Maximum Industry Days to MDUFA IV Decision	180	63			
<b>Average Number of Total Days to MDUFA IV Decision</b>	106.31	74.87			
20th Percentile Total Days to MDUFA IV Decision	60	30			
40th Percentile Total Days to MDUFA IV Decision	88	67			
60th Percentile Total Days to MDUFA IV Decision	108	89			
80th Percentile Total Days to MDUFA IV Decision	147	111			
Maximum Total Days to MDUFA IV Decision	346	153			

**Table 6.6 DNPMD - ODE - CDRH - 510(k) Performance Metric - Rates of SE, NSE, Withdrawal, and Delete Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
510(k) Accepted	227	97			
Number With MDUFA IV Decision	178	31			
Number of SE Decision	170	31			
Number of NSE Decision	8	0			
Number of Withdrawal	10	2			
Number of Deleted	5	0			
Rate of SE Decision	95.51%	100%			
Rate of NSE Decision	4.49%	0%			
Rate of Withdrawal	4.41%	2.06%			
Rate of Deleted	2.20%	0%			

**Table 6.7 DNPMD - ODE - CDRH - 510(k) Performance Metric - Submissions Missing Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number of Submissions that Missed the Goal	5	0			
Mean FDA Days for Submissions that Missed the Goal	111.40	0			
Mean Industry Days for Submissions that Missed the Goal	81	0			

**Table 6.8 DNPMD - ODE - CDRH - LDT 510(k) MDUFA IV Decision Metric**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	0	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision (SE/NSE)	0	0			
MDUFA IV Decision Within 90 FDA Days	0	0			
510(k)s Pending MDUFA IV Decision	0	0			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	N/A	N/A			

**Table 6.9 DNPMD - ODE - CDRH - Conventional IVD (Non-LDT) 510(k) MDUFA IV Decision Metric**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	0	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision (SE/NSE)	0	0			
MDUFA IV Decision Within 90 FDA Days	0	0			
510(k)s Pending MDUFA IV Decision	0	0			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	N/A	N/A			



## Section 6 510(k) Division Level Metric (Excludes Third Party Review)

Table 6.1 DOD - ODE - CDRH - 510(k) Acceptance Review Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	606	303			
Closed Before RTA Action	2	3			
Number Accepted	466	232			
Number Without a RTA and > 15 Days Since Date Received	0	3			
Number Without a RTA and <= 15 Days Since Date Received	0	13			
Number Not Accepted	138	52			
Rate of Submissions Not Accepted for Review	22.85%	18.12%			

Table 6.2 DOD - ODE - CDRH - 510(k) Substantive Interaction Performance Goal

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days
Eligible For SI	593	259			
Deleted or Withdrawn Prior to SI	0	2			
SI Within 60 FDA Days	570	181			
SI Over 60 FDA Days	19	0			
SI Pending Within 60 FDA Days	4	76			
SI Pending Over 60 FDA Days	0	0			
510(k)s NSE Without SI	0	0			
Current SI Performance Percent Within 60 FDA Days	96.77%	100%			

**Table 6.3 DOD - ODE - CDRH - 510(k) Substantive Interaction Metric - Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number of Substantive Interactions	589	181			
Average Number of FDA Days to Substantive Interaction	50.36	45.72			
20th Percentile FDA Days to Substantive Interaction	39	29			
40th Percentile FDA Days to Substantive Interaction	55	49			
60th Percentile FDA Days to Substantive Interaction	57	57			
80th Percentile FDA Days to Substantive Interaction	59	59			
Maximum FDA Days to Substantive Interaction	78	60			

**Table 6.4 DOD - ODE - CDRH - 510(k) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>
510(k)s Accepted	593	259			
Non-MDUFA IV Decision	31	2			
MDUFA IV Decision (SE/NSE)	522	102			
MDUFA IV Decision Within 90 FDA Days	522	102			
510(k)s Pending MDUFA IV Decision	40	155			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	100%	100%			

Table 6.5 DOD - ODE - CDRH - 510(k) Time to MDUFA IV Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.64	1.41			
Number With MDUFA IV Decision	522	102			
<b>Average Number of FDA Days to MDUFA IV Decision</b>	70.37	55.88			
20th Percentile FDA Days to MDUFA IV Decision	51	29			
40th Percentile FDA Days to MDUFA IV Decision	69	48			
60th Percentile FDA Days to MDUFA IV Decision	86	65			
80th Percentile FDA Days to MDUFA IV Decision	89	87			
Maximum FDA Days to MDUFA IV Decision	90	90			
<b>Average Number of Industry Days to MDUFA IV Decision</b>	42.29	9.29			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	6	0			
60th Percentile Industry Days to MDUFA IV Decision	28	2			
80th Percentile Industry Days to MDUFA IV Decision	80	19			
Maximum Industry Days to MDUFA IV Decision	316	77			
<b>Average Number of Total Days to MDUFA IV Decision</b>	112.65	65.18			
20th Percentile Total Days to MDUFA IV Decision	56	29			
40th Percentile Total Days to MDUFA IV Decision	85	53			
60th Percentile Total Days to MDUFA IV Decision	110	77			
80th Percentile Total Days to MDUFA IV Decision	166	96			
Maximum Total Days to MDUFA IV Decision	400	164			

**Table 6.6 DOD - ODE - CDRH - 510(k) Performance Metric - Rates of SE, NSE, Withdrawal, and Delete Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
510(k) Accepted	593	259			
Number With MDUFA IV Decision	522	102			
Number of SE Decision	511	102			
Number of NSE Decision	11	0			
Number of Withdrawal	21	2			
Number of Deleted	10	0			
Rate of SE Decision	97.89%	100%			
Rate of NSE Decision	2.11%	0%			
Rate of Withdrawal	3.54%	0.77%			
Rate of Deleted	1.69%	0%			

**Table 6.7 DOD - ODE - CDRH - 510(k) Performance Metric - Submissions Missing Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 6.8 DOD - ODE - CDRH - LDT 510(k) MDUFA IV Decision Metric**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	0	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision (SE/NSE)	0	0			
MDUFA IV Decision Within 90 FDA Days	0	0			
510(k)s Pending MDUFA IV Decision	0	0			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	N/A	N/A			

**Table 6.9 DOD - ODE - CDRH - Conventional IVD (Non-LDT) 510(k) MDUFA IV Decision Metric**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	0	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision (SE/NSE)	0	0			
MDUFA IV Decision Within 90 FDA Days	0	0			
510(k)s Pending MDUFA IV Decision	0	0			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	N/A	N/A			

## Section 6 510(k) Division Level Metric (Excludes Third Party Review)

Table 6.1 DOED - ODE - CDRH - 510(k) Acceptance Review Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	140	58			
Closed Before RTA Action	0	1			
Number Accepted	112	44			
Number Without a RTA and > 15 Days Since Date Received	0	2			
Number Without a RTA and <= 15 Days Since Date Received	0	3			
Number Not Accepted	28	8			
Rate of Submissions Not Accepted for Review	20.00%	14.81%			

Table 6.2 DOED - ODE - CDRH - 510(k) Substantive Interaction Performance Goal

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days
Eligible For SI	137	49			
Deleted or Withdrawn Prior to SI	2	1			
SI Within 60 FDA Days	133	33			
SI Over 60 FDA Days	0	0			
SI Pending Within 60 FDA Days	1	15			
SI Pending Over 60 FDA Days	0	0			
510(k)s NSE Without SI	1	0			
Current SI Performance Percent Within 60 FDA Days	99.25%	100%			

**Table 6.3 DOED - ODE - CDRH - 510(k) Substantive Interaction Metric - Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number of Substantive Interactions	133	33			
Average Number of FDA Days to Substantive Interaction	51.78	48.36			
20th Percentile FDA Days to Substantive Interaction	48	31			
40th Percentile FDA Days to Substantive Interaction	53	51			
60th Percentile FDA Days to Substantive Interaction	57	56			
80th Percentile FDA Days to Substantive Interaction	59	60			
Maximum FDA Days to Substantive Interaction	60	60			

**Table 6.4 DOED - ODE - CDRH - 510(k) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>
510(k)s Accepted	137	49			
Non-MDUFA IV Decision	13	2			
MDUFA IV Decision (SE/NSE)	116	16			
MDUFA IV Decision Within 90 FDA Days	116	16			
510(k)s Pending MDUFA IV Decision	8	31			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	100%	100%			

Table 6.5 DOED - ODE - CDRH - 510(k) Time to MDUFA IV Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.42	1.44			
Number With MDUFA IV Decision	116	16			
<b>Average Number of FDA Days to MDUFA IV Decision</b>	70.41	59.69			
20th Percentile FDA Days to MDUFA IV Decision	51	47			
40th Percentile FDA Days to MDUFA IV Decision	64	49			
60th Percentile FDA Days to MDUFA IV Decision	86	60			
80th Percentile FDA Days to MDUFA IV Decision	90	84			
Maximum FDA Days to MDUFA IV Decision	90	90			
<b>Average Number of Industry Days to MDUFA IV Decision</b>	32.99	16.81			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	12	11			
80th Percentile Industry Days to MDUFA IV Decision	69	32			
Maximum Industry Days to MDUFA IV Decision	180	78			
<b>Average Number of Total Days to MDUFA IV Decision</b>	103.40	76.50			
20th Percentile Total Days to MDUFA IV Decision	51	49			
40th Percentile Total Days to MDUFA IV Decision	69	56			
60th Percentile Total Days to MDUFA IV Decision	90	89			
80th Percentile Total Days to MDUFA IV Decision	156	107			
Maximum Total Days to MDUFA IV Decision	270	154			



**Table 6.6 DOED - ODE - CDRH - 510(k) Performance Metric - Rates of SE, NSE, Withdrawal, and Delete Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
510(k) Accepted	137	49			
Number With MDUFA IV Decision	116	16			
Number of SE Decision	114	16			
Number of NSE Decision	2	0			
Number of Withdrawal	8	2			
Number of Deleted	5	0			
Rate of SE Decision	98.28%	100%			
Rate of NSE Decision	1.72%	0%			
Rate of Withdrawal	5.84%	4.08%			
Rate of Deleted	3.65%	0%			

**Table 6.7 DOED - ODE - CDRH - 510(k) Performance Metric - Submissions Missing Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 6.8 DOED - ODE - CDRH - LDT 510(k) MDUFA IV Decision Metric**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	0	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision (SE/NSE)	0	0			
MDUFA IV Decision Within 90 FDA Days	0	0			
510(k)s Pending MDUFA IV Decision	0	0			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	N/A	N/A			

**Table 6.9 DOED - ODE - CDRH - Conventional IVD (Non-LDT) 510(k) MDUFA IV Decision Metric**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	0	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision (SE/NSE)	0	0			
MDUFA IV Decision Within 90 FDA Days	0	0			
510(k)s Pending MDUFA IV Decision	0	0			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	N/A	N/A			

## Section 6 510(k) Division Level Metric (Excludes Third Party Review)

Table 6.1 DRGUD - ODE - CDRH - 510(k) Acceptance Review Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	309	161			
Closed Before RTA Action	1	2			
Number Accepted	250	118			
Number Without a RTA and > 15 Days Since Date Received	0	2			
Number Without a RTA and <= 15 Days Since Date Received	0	14			
Number Not Accepted	58	25			
Rate of Submissions Not Accepted for Review	18.83%	17.24%			

Table 6.2 DRGUD - ODE - CDRH - 510(k) Substantive Interaction Performance Goal

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days
Eligible For SI	299	129			
Deleted or Withdrawn Prior to SI	0	0			
SI Within 60 FDA Days	292	89			
SI Over 60 FDA Days	3	0			
SI Pending Within 60 FDA Days	1	40			
SI Pending Over 60 FDA Days	0	0			
510(k)s NSE Without SI	3	0			
Current SI Performance Percent Within 60 FDA Days	97.99%	100%			

**Table 6.3 DRGUD - ODE - CDRH - 510(k) Substantive Interaction Metric - Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number of Substantive Interactions	295	89			
Average Number of FDA Days to Substantive Interaction	49.90	50.46			
20th Percentile FDA Days to Substantive Interaction	42	42			
40th Percentile FDA Days to Substantive Interaction	52	53			
60th Percentile FDA Days to Substantive Interaction	58	58			
80th Percentile FDA Days to Substantive Interaction	60	60			
Maximum FDA Days to Substantive Interaction	64	60			

**Table 6.4 DRGUD - ODE - CDRH - 510(k) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>
510(k)s Accepted	299	129			
Non-MDUFA IV Decision	24	1			
MDUFA IV Decision (SE/NSE)	249	28			
MDUFA IV Decision Within 90 FDA Days	248	28			
510(k)s Pending MDUFA IV Decision	26	100			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	100%	100%			

Table 6.5 DRGUD - ODE - CDRH - 510(k) Time to MDUFA IV Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.65	1.32			
Number With MDUFA IV Decision	249	28			
<b>Average Number of FDA Days to MDUFA IV Decision</b>	71.76	54.11			
20th Percentile FDA Days to MDUFA IV Decision	56	29			
40th Percentile FDA Days to MDUFA IV Decision	77	51			
60th Percentile FDA Days to MDUFA IV Decision	87	58			
80th Percentile FDA Days to MDUFA IV Decision	89	81			
Maximum FDA Days to MDUFA IV Decision	92	90			
<b>Average Number of Industry Days to MDUFA IV Decision</b>	61.67	9.79			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	13	0			
60th Percentile Industry Days to MDUFA IV Decision	57	0			
80th Percentile Industry Days to MDUFA IV Decision	145	19			
Maximum Industry Days to MDUFA IV Decision	182	70			
<b>Average Number of Total Days to MDUFA IV Decision</b>	133.43	63.89			
20th Percentile Total Days to MDUFA IV Decision	59	29			
40th Percentile Total Days to MDUFA IV Decision	90	51			
60th Percentile Total Days to MDUFA IV Decision	138	66			
80th Percentile Total Days to MDUFA IV Decision	228	98			
Maximum Total Days to MDUFA IV Decision	271	128			

**Table 6.6 DRGUD - ODE - CDRH - 510(k) Performance Metric - Rates of SE, NSE, Withdrawal, and Delete Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
510(k) Accepted	299	129			
Number With MDUFA IV Decision	249	28			
Number of SE Decision	232	28			
Number of NSE Decision	17	0			
Number of Withdrawal	11	0			
Number of Deleted	13	0			
Rate of SE Decision	93.17%	100%			
Rate of NSE Decision	6.83%	0%			
Rate of Withdrawal	3.68%	0%			
Rate of Deleted	4.35%	0%			

**Table 6.7 DRGUD - ODE - CDRH - 510(k) Performance Metric - Submissions Missing Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number of Submissions that Missed the Goal	1	0			
Mean FDA Days for Submissions that Missed the Goal	92.00	0			
Mean Industry Days for Submissions that Missed the Goal	35	0			

**Table 6.8 DRGUD - ODE - CDRH - LDT 510(k) MDUFA IV Decision Metric**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	0	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision (SE/NSE)	0	0			
MDUFA IV Decision Within 90 FDA Days	0	0			
510(k)s Pending MDUFA IV Decision	0	0			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	N/A	N/A			

**Table 6.9 DRGUD - ODE - CDRH - Conventional IVD (Non-LDT) 510(k) MDUFA IV Decision Metric**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	0	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision (SE/NSE)	0	0			
MDUFA IV Decision Within 90 FDA Days	0	0			
510(k)s Pending MDUFA IV Decision	0	0			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	N/A	N/A			

## Section 6 510(k) Division Level Metric (Excludes Third Party Review)

Table 6.1 DSD - ODE - CDRH - 510(k) Acceptance Review Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	417	208			
Closed Before RTA Action	2	0			
Number Accepted	288	120			
Number Without a RTA and > 15 Days Since Date Received	5	3			
Number Without a RTA and <= 15 Days Since Date Received	0	17			
Number Not Accepted	122	68			
Rate of Submissions Not Accepted for Review	29.40%	35.60%			

Table 6.2 DSD - ODE - CDRH - 510(k) Substantive Interaction Performance Goal

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days
Eligible For SI	385	146			
Deleted or Withdrawn Prior to SI	0	1			
SI Within 60 FDA Days	377	105			
SI Over 60 FDA Days	4	1			
SI Pending Within 60 FDA Days	4	39			
SI Pending Over 60 FDA Days	0	0			
510(k)s NSE Without SI	0	0			
Current SI Performance Percent Within 60 FDA Days	98.95%	99.06%			



**Table 6.3 DSD - ODE - CDRH - 510(k) Substantive Interaction Metric - Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number of Substantive Interactions	381	106			
Average Number of FDA Days to Substantive Interaction	52.15	50.23			
20th Percentile FDA Days to Substantive Interaction	49	35			
40th Percentile FDA Days to Substantive Interaction	57	56			
60th Percentile FDA Days to Substantive Interaction	58	58			
80th Percentile FDA Days to Substantive Interaction	60	59			
Maximum FDA Days to Substantive Interaction	69	64			

**Table 6.4 DSD - ODE - CDRH - 510(k) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>
510(k)s Accepted	385	146			
Non-MDUFA IV Decision	42	2			
MDUFA IV Decision (SE/NSE)	310	61			
MDUFA IV Decision Within 90 FDA Days	306	61			
510(k)s Pending MDUFA IV Decision	33	83			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	98.71%	100%			

Table 6.5 DSD - ODE - CDRH - 510(k) Time to MDUFA IV Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.47	1.18			
Number With MDUFA IV Decision	310	61			
<b>Average Number of FDA Days to MDUFA IV Decision</b>	70.68	55.61			
20th Percentile FDA Days to MDUFA IV Decision	51	28			
40th Percentile FDA Days to MDUFA IV Decision	75	49			
60th Percentile FDA Days to MDUFA IV Decision	87	59			
80th Percentile FDA Days to MDUFA IV Decision	89	86			
Maximum FDA Days to MDUFA IV Decision	163	90			
<b>Average Number of Industry Days to MDUFA IV Decision</b>	35.01	4.15			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	14	0			
80th Percentile Industry Days to MDUFA IV Decision	71	0			
Maximum Industry Days to MDUFA IV Decision	200	53			
<b>Average Number of Total Days to MDUFA IV Decision</b>	105.69	59.75			
20th Percentile Total Days to MDUFA IV Decision	55	28			
40th Percentile Total Days to MDUFA IV Decision	82	50			
60th Percentile Total Days to MDUFA IV Decision	96	60			
80th Percentile Total Days to MDUFA IV Decision	160	90			
Maximum Total Days to MDUFA IV Decision	290	141			

**Table 6.6 DSD - ODE - CDRH - 510(k) Performance Metric - Rates of SE, NSE, Withdrawal, and Delete Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
510(k) Accepted	385	146			
Number With MDUFA IV Decision	310	61			
Number of SE Decision	302	58			
Number of NSE Decision	8	3			
Number of Withdrawal	23	1			
Number of Deleted	18	0			
Rate of SE Decision	97.42%	95.08%			
Rate of NSE Decision	2.58%	4.92%			
Rate of Withdrawal	5.97%	0.68%			
Rate of Deleted	4.68%	0%			

**Table 6.7 DSD - ODE - CDRH - 510(k) Performance Metric - Submissions Missing Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number of Submissions that Missed the Goal	4	0			
Mean FDA Days for Submissions that Missed the Goal	112.00	0			
Mean Industry Days for Submissions that Missed the Goal	61	0			

**Table 6.8 DSD - ODE - CDRH - LDT 510(k) MDUFA IV Decision Metric**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	0	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision (SE/NSE)	0	0			
MDUFA IV Decision Within 90 FDA Days	0	0			
510(k)s Pending MDUFA IV Decision	0	0			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	N/A	N/A			

**Table 6.9 DSD - ODE - CDRH - Conventional IVD (Non-LDT) 510(k) MDUFA IV Decision Metric**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	0	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision (SE/NSE)	0	0			
MDUFA IV Decision Within 90 FDA Days	0	0			
510(k)s Pending MDUFA IV Decision	0	0			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	N/A	N/A			

## Section 6 510(k) Division Level Metric (Excludes Third Party Review)

Table 6.1 DCTD - OIR - CDRH - 510(k) Acceptance Review Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	142	56			
Closed Before RTA Action	3	1			
Number Accepted	109	38			
Number Without a RTA and > 15 Days Since Date Received	1	1			
Number Without a RTA and <= 15 Days Since Date Received	0	3			
Number Not Accepted	29	13			
Rate of Submissions Not Accepted for Review	20.86%	25.00%			

Table 6.2 DCTD - OIR - CDRH - 510(k) Substantive Interaction Performance Goal

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days
Eligible For SI	133	44			
Deleted or Withdrawn Prior to SI	0	0			
SI Within 60 FDA Days	130	31			
SI Over 60 FDA Days	0	0			
SI Pending Within 60 FDA Days	2	13			
SI Pending Over 60 FDA Days	0	0			
510(k)s NSE Without SI	1	0			
Current SI Performance Percent Within 60 FDA Days	99.24%	100%			

**Table 6.3 DCTD - OIR - CDRH - 510(k) Substantive Interaction Metric - Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number of Substantive Interactions	130	31			
Average Number of FDA Days to Substantive Interaction	49.64	49.55			
20th Percentile FDA Days to Substantive Interaction	44	44			
40th Percentile FDA Days to Substantive Interaction	51	51			
60th Percentile FDA Days to Substantive Interaction	56	58			
80th Percentile FDA Days to Substantive Interaction	59	60			
Maximum FDA Days to Substantive Interaction	60	60			

**Table 6.4 DCTD - OIR - CDRH - 510(k) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>
510(k)s Accepted	133	44			
Non-MDUFA IV Decision	24	0			
MDUFA IV Decision (SE/NSE)	90	16			
MDUFA IV Decision Within 90 FDA Days	90	16			
510(k)s Pending MDUFA IV Decision	19	28			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	100%	100%			

Table 6.5 DCTD - OIR - CDRH - 510(k) Time to MDUFA IV Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.64	1.06			
Number With MDUFA IV Decision	90	16			
<b>Average Number of FDA Days to MDUFA IV Decision</b>	72.57	53.00			
20th Percentile FDA Days to MDUFA IV Decision	56	28			
40th Percentile FDA Days to MDUFA IV Decision	82	44			
60th Percentile FDA Days to MDUFA IV Decision	88	58			
80th Percentile FDA Days to MDUFA IV Decision	90	81			
Maximum FDA Days to MDUFA IV Decision	90	90			
<b>Average Number of Industry Days to MDUFA IV Decision</b>	68.24	2.19			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	8	0			
60th Percentile Industry Days to MDUFA IV Decision	78	0			
80th Percentile Industry Days to MDUFA IV Decision	161	0			
Maximum Industry Days to MDUFA IV Decision	231	35			
<b>Average Number of Total Days to MDUFA IV Decision</b>	140.81	55.19			
20th Percentile Total Days to MDUFA IV Decision	56	28			
40th Percentile Total Days to MDUFA IV Decision	92	44			
60th Percentile Total Days to MDUFA IV Decision	168	58			
80th Percentile Total Days to MDUFA IV Decision	240	81			
Maximum Total Days to MDUFA IV Decision	321	124			

**Table 6.6 DCTD - OIR - CDRH - 510(k) Performance Metric - Rates of SE, NSE, Withdrawal, and Delete Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
510(k) Accepted	133	44			
Number With MDUFA IV Decision	90	16			
Number of SE Decision	87	16			
Number of NSE Decision	3	0			
Number of Withdrawal	15	0			
Number of Deleted	8	0			
Rate of SE Decision	96.67%	100%			
Rate of NSE Decision	3.33%	0%			
Rate of Withdrawal	11.28%	0%			
Rate of Deleted	6.02%	0%			

**Table 6.7 DCTD - OIR - CDRH - 510(k) Performance Metric - Submissions Missing Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			



**Table 6.8 DCTD - OIR - CDRH - LDT 510(k) MDUFA IV Decision Metric**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	0	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision (SE/NSE)	0	0			
MDUFA IV Decision Within 90 FDA Days	0	0			
510(k)s Pending MDUFA IV Decision	0	0			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	N/A	N/A			

**Table 6.9 DCTD - OIR - CDRH - Conventional IVD (Non-LDT) 510(k) MDUFA IV Decision Metric**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	133	44			
Non-MDUFA IV Decision	24	0			
MDUFA IV Decision (SE/NSE)	90	16			
MDUFA IV Decision Within 90 FDA Days	90	16			
510(k)s Pending MDUFA IV Decision	19	28			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	100%	100%			

## Section 6 510(k) Division Level Metric (Excludes Third Party Review)

Table 6.1 DIHD - OIR - CDRH - 510(k) Acceptance Review Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	50	31			
Closed Before RTA Action	0	0			
Number Accepted	43	16			
Number Without a RTA and > 15 Days Since Date Received	0	2			
Number Without a RTA and <= 15 Days Since Date Received	0	4			
Number Not Accepted	7	9			
Rate of Submissions Not Accepted for Review	14.00%	33.33%			

Table 6.2 DIHD - OIR - CDRH - 510(k) Substantive Interaction Performance Goal

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days
Eligible For SI	46	20			
Deleted or Withdrawn Prior to SI	1	0			
SI Within 60 FDA Days	44	18			
SI Over 60 FDA Days	1	0			
SI Pending Within 60 FDA Days	0	2			
SI Pending Over 60 FDA Days	0	0			
510(k)s NSE Without SI	0	0			
Current SI Performance Percent Within 60 FDA Days	97.78%	100%			

**Table 6.3 DIHD - OIR - CDRH - 510(k) Substantive Interaction Metric - Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number of Substantive Interactions	45	18			
Average Number of FDA Days to Substantive Interaction	52.67	53.83			
20th Percentile FDA Days to Substantive Interaction	48	52			
40th Percentile FDA Days to Substantive Interaction	57	57			
60th Percentile FDA Days to Substantive Interaction	59	60			
80th Percentile FDA Days to Substantive Interaction	60	60			
Maximum FDA Days to Substantive Interaction	61	60			

**Table 6.4 DIHD - OIR - CDRH - 510(k) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>
510(k)s Accepted	46	20			
Non-MDUFA IV Decision	3	0			
MDUFA IV Decision (SE/NSE)	42	8			
MDUFA IV Decision Within 90 FDA Days	41	8			
510(k)s Pending MDUFA IV Decision	1	12			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	97.62%	100%			

Table 6.5 DIHD - OIR - CDRH - 510(k) Time to MDUFA IV Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.55	1.13			
Number With MDUFA IV Decision	42	8			
<b>Average Number of FDA Days to MDUFA IV Decision</b>	76.55	74.75			
20th Percentile FDA Days to MDUFA IV Decision	70	59			
40th Percentile FDA Days to MDUFA IV Decision	88	83			
60th Percentile FDA Days to MDUFA IV Decision	90	90			
80th Percentile FDA Days to MDUFA IV Decision	90	90			
Maximum FDA Days to MDUFA IV Decision	93	90			
<b>Average Number of Industry Days to MDUFA IV Decision</b>	66.71	10.38			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	81	0			
80th Percentile Industry Days to MDUFA IV Decision	167	0			
Maximum Industry Days to MDUFA IV Decision	202	83			
<b>Average Number of Total Days to MDUFA IV Decision</b>	143.26	85.13			
20th Percentile Total Days to MDUFA IV Decision	75	59			
40th Percentile Total Days to MDUFA IV Decision	90	86			
60th Percentile Total Days to MDUFA IV Decision	171	90			
80th Percentile Total Days to MDUFA IV Decision	255	90			
Maximum Total Days to MDUFA IV Decision	295	169			

**Table 6.6 DIHD - OIR - CDRH - 510(k) Performance Metric - Rates of SE, NSE, Withdrawal, and Delete Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
510(k) Accepted	46	20			
Number With MDUFA IV Decision	42	8			
Number of SE Decision	39	8			
Number of NSE Decision	3	0			
Number of Withdrawal	2	0			
Number of Deleted	1	0			
Rate of SE Decision	92.86%	100%			
Rate of NSE Decision	7.14%	0%			
Rate of Withdrawal	4.35%	0%			
Rate of Deleted	2.17%	0%			

**Table 6.7 DIHD - OIR - CDRH - 510(k) Performance Metric - Submissions Missing Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number of Submissions that Missed the Goal	1	0			
Mean FDA Days for Submissions that Missed the Goal	93.00	0			
Mean Industry Days for Submissions that Missed the Goal	202	0			

**Table 6.8 DIHD - OIR - CDRH - LDT 510(k) MDUFA IV Decision Metric**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	0	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision (SE/NSE)	0	0			
MDUFA IV Decision Within 90 FDA Days	0	0			
510(k)s Pending MDUFA IV Decision	0	0			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	N/A	N/A			

**Table 6.9 DIHD - OIR - CDRH - Conventional IVD (Non-LDT) 510(k) MDUFA IV Decision Metric**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	46	20			
Non-MDUFA IV Decision	3	0			
MDUFA IV Decision (SE/NSE)	42	8			
MDUFA IV Decision Within 90 FDA Days	41	8			
510(k)s Pending MDUFA IV Decision	1	12			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	97.62%	100%			

## Section 6 510(k) Division Level Metric (Excludes Third Party Review)

Table 6.1 DMD - OIR - CDRH - 510(k) Acceptance Review Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	89	52			
Closed Before RTA Action	0	0			
Number Accepted	86	51			
Number Without a RTA and > 15 Days Since Date Received	0	1			
Number Without a RTA and <= 15 Days Since Date Received	0	0			
Number Not Accepted	3	0			
Rate of Submissions Not Accepted for Review	3.37%	0%			

Table 6.2 DMD - OIR - CDRH - 510(k) Substantive Interaction Performance Goal

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days
Eligible For SI	87	52			
Deleted or Withdrawn Prior to SI	0	0			
SI Within 60 FDA Days	87	32			
SI Over 60 FDA Days	0	0			
SI Pending Within 60 FDA Days	0	20			
SI Pending Over 60 FDA Days	0	0			
510(k)s NSE Without SI	0	0			
Current SI Performance Percent Within 60 FDA Days	100%	100%			

**Table 6.3 DMD - OIR - CDRH - 510(k) Substantive Interaction Metric - Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number of Substantive Interactions	87	32			
Average Number of FDA Days to Substantive Interaction	50.67	48.06			
20th Percentile FDA Days to Substantive Interaction	41	31			
40th Percentile FDA Days to Substantive Interaction	57	54			
60th Percentile FDA Days to Substantive Interaction	58	57			
80th Percentile FDA Days to Substantive Interaction	59	59			
Maximum FDA Days to Substantive Interaction	60	60			

**Table 6.4 DMD - OIR - CDRH - 510(k) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>
510(k)s Accepted	87	52			
Non-MDUFA IV Decision	4	0			
MDUFA IV Decision (SE/NSE)	79	26			
MDUFA IV Decision Within 90 FDA Days	79	26			
510(k)s Pending MDUFA IV Decision	4	26			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	100%	100%			



**Table 6.5 DMD - OIR - CDRH - 510(k) Time to MDUFA IV Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Average Review Cycles	1.22	1.08			
Number With MDUFA IV Decision	79	26			
<b>Average Number of FDA Days to MDUFA IV Decision</b>	69.06	60.96			
20th Percentile FDA Days to MDUFA IV Decision	38	38			
40th Percentile FDA Days to MDUFA IV Decision	74	56			
60th Percentile FDA Days to MDUFA IV Decision	87	72			
80th Percentile FDA Days to MDUFA IV Decision	89	84			
Maximum FDA Days to MDUFA IV Decision	90	90			
<b>Average Number of Industry Days to MDUFA IV Decision</b>	21.48	2.69			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	0	0			
80th Percentile Industry Days to MDUFA IV Decision	7	0			
Maximum Industry Days to MDUFA IV Decision	181	62			
<b>Average Number of Total Days to MDUFA IV Decision</b>	90.54	63.65			
20th Percentile Total Days to MDUFA IV Decision	42	38			
40th Percentile Total Days to MDUFA IV Decision	76	59			
60th Percentile Total Days to MDUFA IV Decision	88	77			
80th Percentile Total Days to MDUFA IV Decision	90	88			
Maximum Total Days to MDUFA IV Decision	271	105			

**Table 6.6 DMD - OIR - CDRH - 510(k) Performance Metric - Rates of SE, NSE, Withdrawal, and Delete Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
510(k) Accepted	87	52			
Number With MDUFA IV Decision	79	26			
Number of SE Decision	79	26			
Number of NSE Decision	0	0			
Number of Withdrawal	2	0			
Number of Deleted	2	0			
Rate of SE Decision	100%	100%			
Rate of NSE Decision	0%	0%			
Rate of Withdrawal	2.30%	0%			
Rate of Deleted	2.30%	0%			

**Table 6.7 DMD - OIR - CDRH - 510(k) Performance Metric - Submissions Missing Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 6.8 DMD - OIR - CDRH - LDT 510(k) MDUFA IV Decision Metric**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	1	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision (SE/NSE)	1	0			
MDUFA IV Decision Within 90 FDA Days	1	0			
510(k)s Pending MDUFA IV Decision	0	0			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	100%	N/A			

**Table 6.9 DMD - OIR - CDRH - Conventional IVD (Non-LDT) 510(k) MDUFA IV Decision Metric**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	86	52			
Non-MDUFA IV Decision	4	0			
MDUFA IV Decision (SE/NSE)	78	26			
MDUFA IV Decision Within 90 FDA Days	78	26			
510(k)s Pending MDUFA IV Decision	4	26			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	100%	100%			

## Section 6 510(k) Division Level Metric (Excludes Third Party Review)

Table 6.1 DMGP - OIR - CDRH - 510(k) Acceptance Review Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	8	9			
Closed Before RTA Action	0	0			
Number Accepted	6	8			
Number Without a RTA and > 15 Days Since Date Received	0	0			
Number Without a RTA and <= 15 Days Since Date Received	0	0			
Number Not Accepted	2	1			
Rate of Submissions Not Accepted for Review	25.00%	11.11%			

Table 6.2 DMGP - OIR - CDRH - 510(k) Substantive Interaction Performance Goal

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days
Eligible For SI	7	8			
Deleted or Withdrawn Prior to SI	0	1			
SI Within 60 FDA Days	7	4			
SI Over 60 FDA Days	0	0			
SI Pending Within 60 FDA Days	0	3			
SI Pending Over 60 FDA Days	0	0			
510(k)s NSE Without SI	0	0			
Current SI Performance Percent Within 60 FDA Days	100%	100%			

**Table 6.3 DMGP - OIR - CDRH - 510(k) Substantive Interaction Metric - Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number of Substantive Interactions	7	4			
Average Number of FDA Days to Substantive Interaction	50.00	41.25			
20th Percentile FDA Days to Substantive Interaction	42	29			
40th Percentile FDA Days to Substantive Interaction	55	34			
60th Percentile FDA Days to Substantive Interaction	58	45			
80th Percentile FDA Days to Substantive Interaction	59	53			
Maximum FDA Days to Substantive Interaction	59	58			

**Table 6.4 DMGP - OIR - CDRH - 510(k) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>
510(k)s Accepted	7	8			
Non-MDUFA IV Decision	2	1			
MDUFA IV Decision (SE/NSE)	4	3			
MDUFA IV Decision Within 90 FDA Days	4	3			
510(k)s Pending MDUFA IV Decision	1	4			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	100%	100%			

Table 6.5 DMGP - OIR - CDRH - 510(k) Time to MDUFA IV Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.75	1.33			
Number With MDUFA IV Decision	4	3			
<b>Average Number of FDA Days to MDUFA IV Decision</b>	59.50	48.67			
20th Percentile FDA Days to MDUFA IV Decision	44	29			
40th Percentile FDA Days to MDUFA IV Decision	50	30			
60th Percentile FDA Days to MDUFA IV Decision	59	42			
80th Percentile FDA Days to MDUFA IV Decision	73	65			
Maximum FDA Days to MDUFA IV Decision	90	88			
<b>Average Number of Industry Days to MDUFA IV Decision</b>	48.00	6.33			
20th Percentile Industry Days to MDUFA IV Decision	5	0			
40th Percentile Industry Days to MDUFA IV Decision	15	0			
60th Percentile Industry Days to MDUFA IV Decision	34	4			
80th Percentile Industry Days to MDUFA IV Decision	81	11			
Maximum Industry Days to MDUFA IV Decision	143	19			
<b>Average Number of Total Days to MDUFA IV Decision</b>	107.50	55.00			
20th Percentile Total Days to MDUFA IV Decision	58	29			
40th Percentile Total Days to MDUFA IV Decision	74	30			
60th Percentile Total Days to MDUFA IV Decision	84	45			
80th Percentile Total Days to MDUFA IV Decision	145	76			
Maximum Total Days to MDUFA IV Decision	233	107			

**Table 6.6 DMGP - OIR - CDRH - 510(k) Performance Metric - Rates of SE, NSE, Withdrawal, and Delete Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
510(k) Accepted	7	8			
Number With MDUFA IV Decision	4	3			
Number of SE Decision	3	3			
Number of NSE Decision	1	0			
Number of Withdrawal	1	1			
Number of Deleted	1	0			
Rate of SE Decision	75.00%	100%			
Rate of NSE Decision	25.00%	0%			
Rate of Withdrawal	14.29%	12.50%			
Rate of Deleted	14.29%	0%			

**Table 6.7 DMGP - OIR - CDRH - 510(k) Performance Metric - Submissions Missing Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 6.8 DMGP - OIR - CDRH - LDT 510(k) MDUFA IV Decision Metric**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	1	1			
Non-MDUFA IV Decision	1	0			
MDUFA IV Decision (SE/NSE)	0	0			
MDUFA IV Decision Within 90 FDA Days	0	0			
510(k)s Pending MDUFA IV Decision	0	1			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	N/A	N/A			

**Table 6.9 DMGP - OIR - CDRH - Conventional IVD (Non-LDT) 510(k) MDUFA IV Decision Metric**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	6	7			
Non-MDUFA IV Decision	1	1			
MDUFA IV Decision (SE/NSE)	4	3			
MDUFA IV Decision Within 90 FDA Days	4	3			
510(k)s Pending MDUFA IV Decision	1	3			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	100%	100%			



## Section 6 510(k) Division Level Metric (Excludes Third Party Review)

Table 6.1 DRH - OIR - CDRH - 510(k) Acceptance Review Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	391	190			
Closed Before RTA Action	0	1			
Number Accepted	348	144			
Number Without a RTA and > 15 Days Since Date Received	1	2			
Number Without a RTA and <= 15 Days Since Date Received	0	9			
Number Not Accepted	42	34			
Rate of Submissions Not Accepted for Review	10.74%	18.89%			

Table 6.2 DRH - OIR - CDRH - 510(k) Substantive Interaction Performance Goal

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days
Eligible For SI	385	163			
Deleted or Withdrawn Prior to SI	1	0			
SI Within 60 FDA Days	384	136			
SI Over 60 FDA Days	0	0			
SI Pending Within 60 FDA Days	0	27			
SI Pending Over 60 FDA Days	0	0			
510(k)s NSE Without SI	0	0			
Current SI Performance Percent Within 60 FDA Days	100%	100%			

**Table 6.3 DRH - OIR - CDRH - 510(k) Substantive Interaction Metric - Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number of Substantive Interactions	384	136			
Average Number of FDA Days to Substantive Interaction	43.70	44.38			
20th Percentile FDA Days to Substantive Interaction	29	29			
40th Percentile FDA Days to Substantive Interaction	42	47			
60th Percentile FDA Days to Substantive Interaction	52	53			
80th Percentile FDA Days to Substantive Interaction	57	57			
Maximum FDA Days to Substantive Interaction	60	60			

**Table 6.4 DRH - OIR - CDRH - 510(k) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>
510(k)s Accepted	385	163			
Non-MDUFA IV Decision	11	2			
MDUFA IV Decision (SE/NSE)	361	88			
MDUFA IV Decision Within 90 FDA Days	361	88			
510(k)s Pending MDUFA IV Decision	13	73			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	100%	100%			

Table 6.5 DRH - OIR - CDRH - 510(k) Time to MDUFA IV Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.49	1.25			
Number With MDUFA IV Decision	361	88			
<b>Average Number of FDA Days to MDUFA IV Decision</b>	58.24	48.52			
20th Percentile FDA Days to MDUFA IV Decision	29	25			
40th Percentile FDA Days to MDUFA IV Decision	55	35			
60th Percentile FDA Days to MDUFA IV Decision	72	57			
80th Percentile FDA Days to MDUFA IV Decision	84	69			
Maximum FDA Days to MDUFA IV Decision	90	90			
<b>Average Number of Industry Days to MDUFA IV Decision</b>	29.92	8.01			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	17	0			
80th Percentile Industry Days to MDUFA IV Decision	54	13			
Maximum Industry Days to MDUFA IV Decision	181	78			
<b>Average Number of Total Days to MDUFA IV Decision</b>	88.16	56.53			
20th Percentile Total Days to MDUFA IV Decision	29	25			
40th Percentile Total Days to MDUFA IV Decision	57	35			
60th Percentile Total Days to MDUFA IV Decision	91	58			
80th Percentile Total Days to MDUFA IV Decision	133	87			
Maximum Total Days to MDUFA IV Decision	270	139			

**Table 6.6 DRH - OIR - CDRH - 510(k) Performance Metric - Rates of SE, NSE, Withdrawal, and Delete Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
510(k) Accepted	385	163			
Number With MDUFA IV Decision	361	88			
Number of SE Decision	351	88			
Number of NSE Decision	10	0			
Number of Withdrawal	5	2			
Number of Deleted	5	0			
Rate of SE Decision	97.23%	100%			
Rate of NSE Decision	2.77%	0%			
Rate of Withdrawal	1.30%	1.23%			
Rate of Deleted	1.30%	0%			

**Table 6.7 DRH - OIR - CDRH - 510(k) Performance Metric - Submissions Missing Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 6.8 DRH - OIR - CDRH - LDT 510(k) MDUFA IV Decision Metric**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	0	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision (SE/NSE)	0	0			
MDUFA IV Decision Within 90 FDA Days	0	0			
510(k)s Pending MDUFA IV Decision	0	0			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	N/A	N/A			

**Table 6.9 DRH - OIR - CDRH - Conventional IVD (Non-LDT) 510(k) MDUFA IV Decision Metric**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	0	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision (SE/NSE)	0	0			
MDUFA IV Decision Within 90 FDA Days	0	0			
510(k)s Pending MDUFA IV Decision	0	0			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	N/A	N/A			

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**Section 7 510(k) Annual General Metrics** - Annual Metrics and Goals will be reported in the Annual Report.

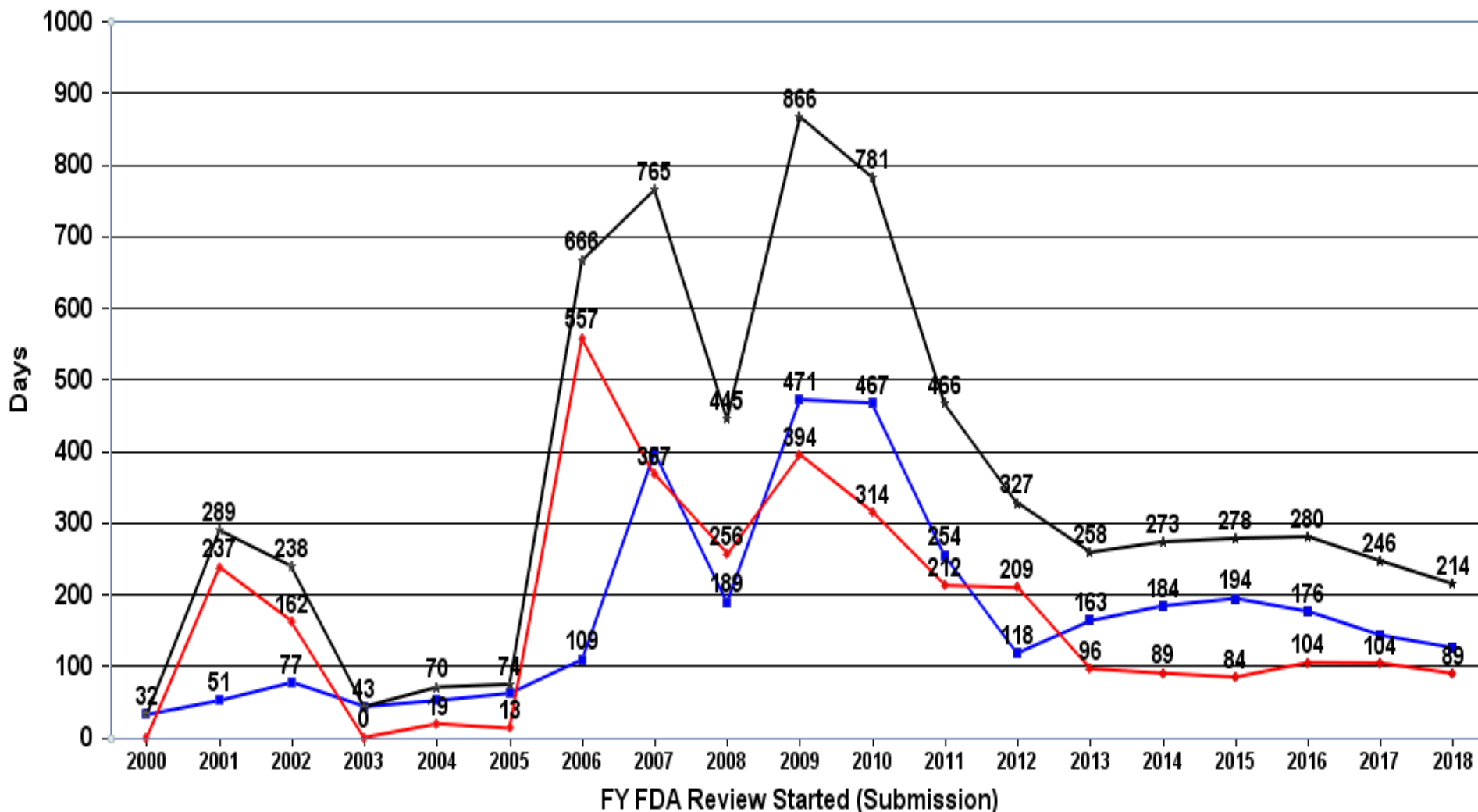
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# De Novos

## Q2FY19

### De Novo Average Days to MDUFA Decision as of: 3/31/19

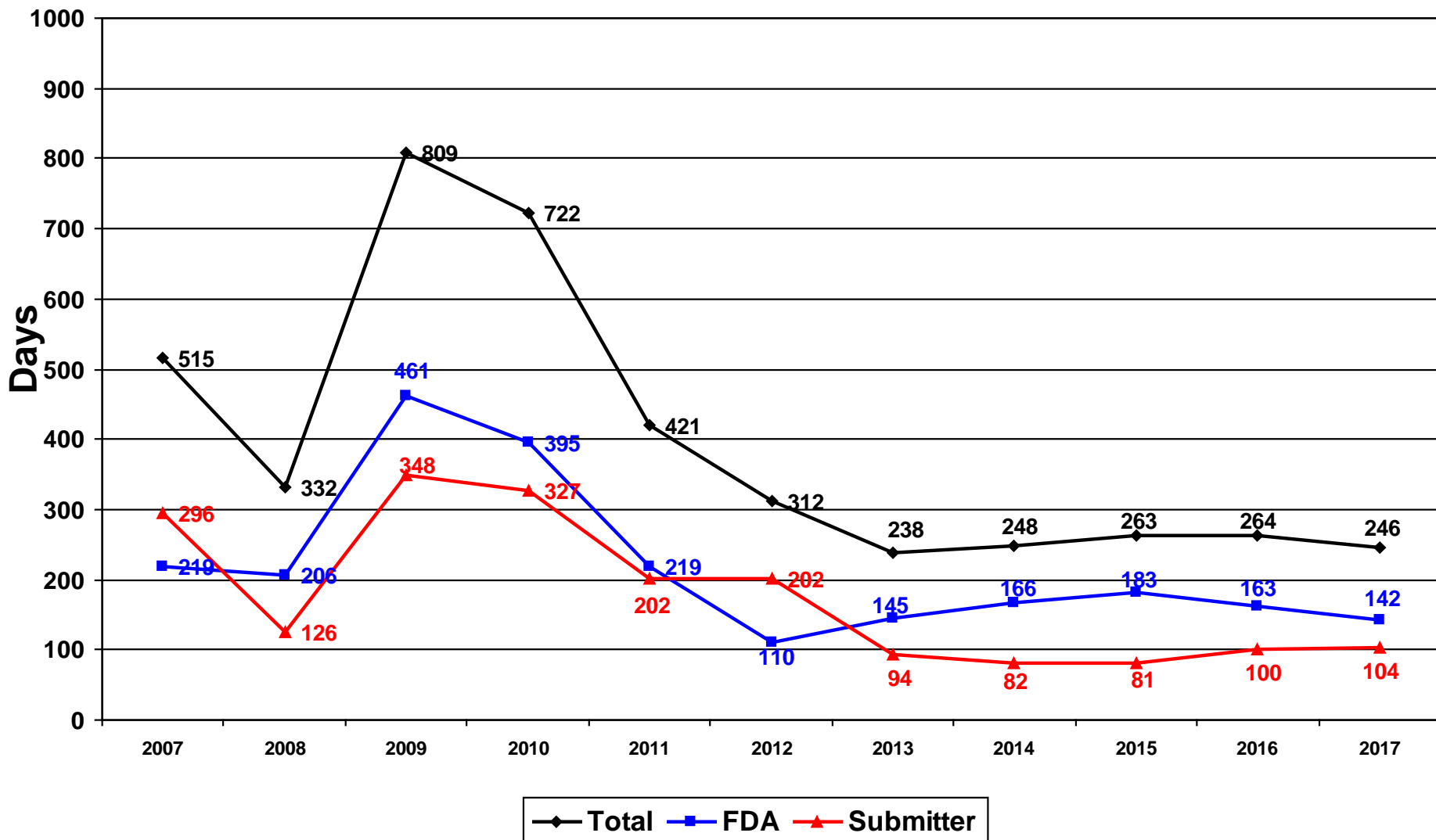


Cohorts not yet closed: 2017: 95.96%; 2018: 73.21%

■ Avg FDA Days to MDUFA Decision ♦ Avg MFR Days to MDUFA Decision ★ Avg Total Elapsed Days to MDUFA Decision

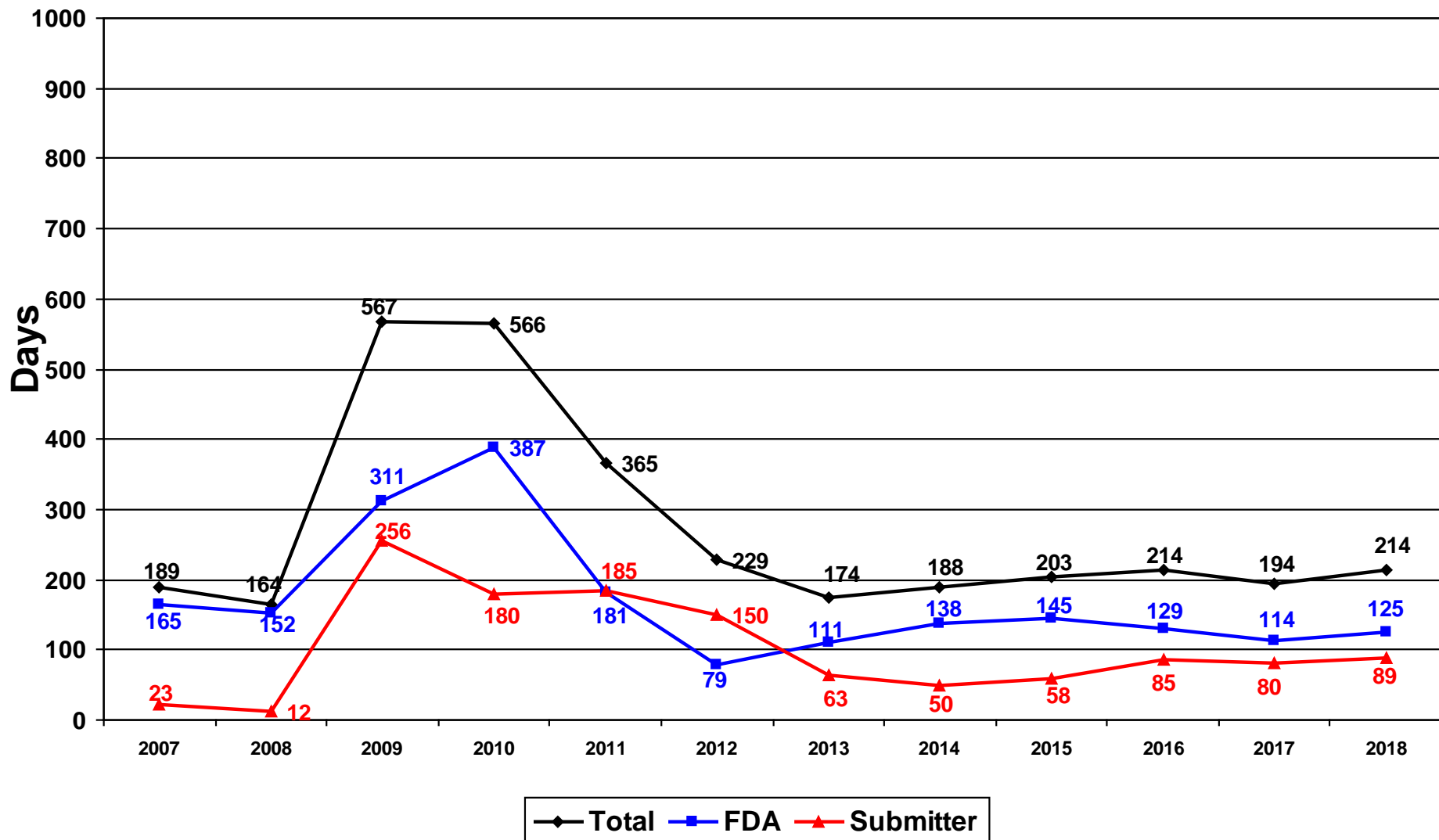
# Average Time to MDUFA Decision: De Novos\*

(96% closure comparison)

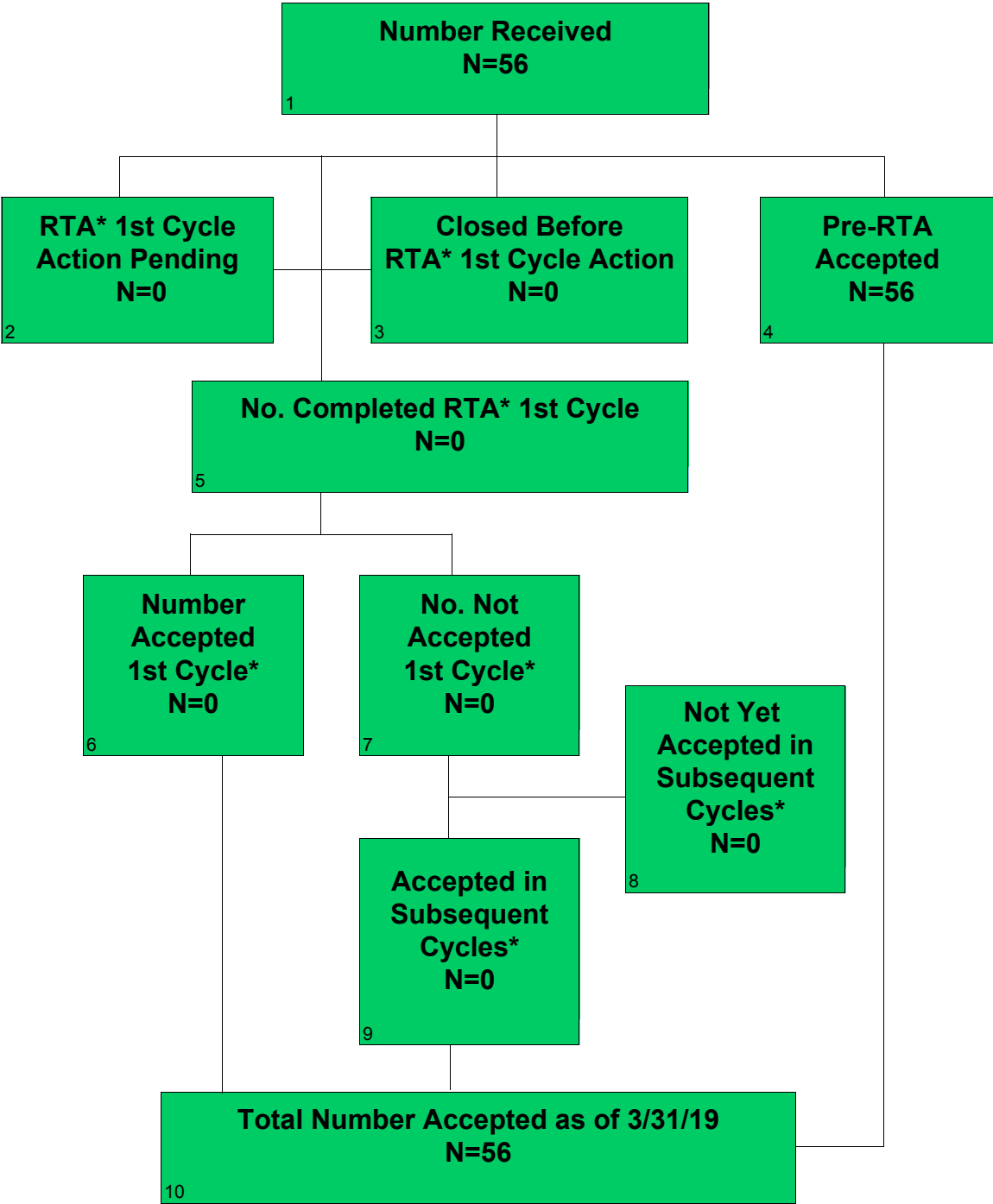


# Average Time to MDUFA Decision: De Novos\*

(73.2% closure comparison)



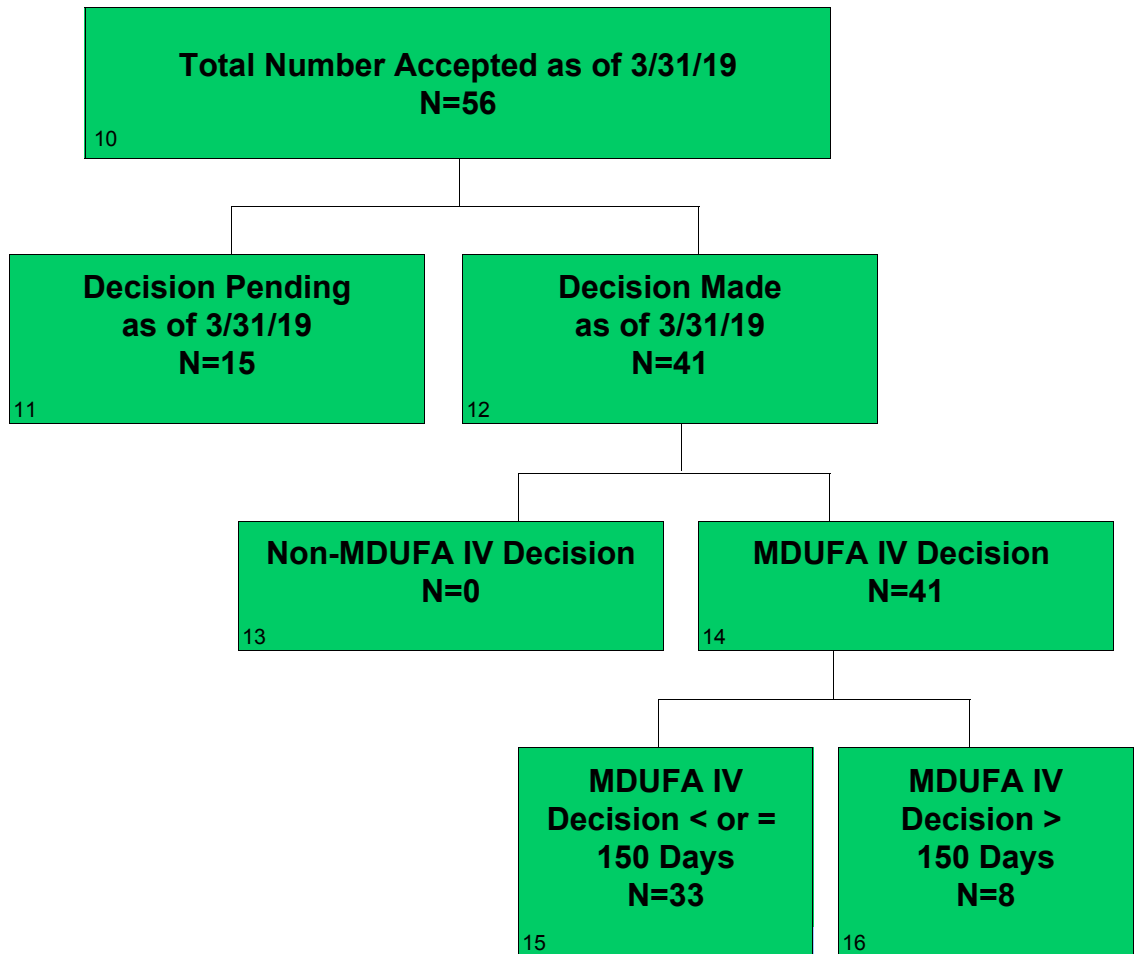
# CDRH De Novo - FY 2018 as of 3/31/19



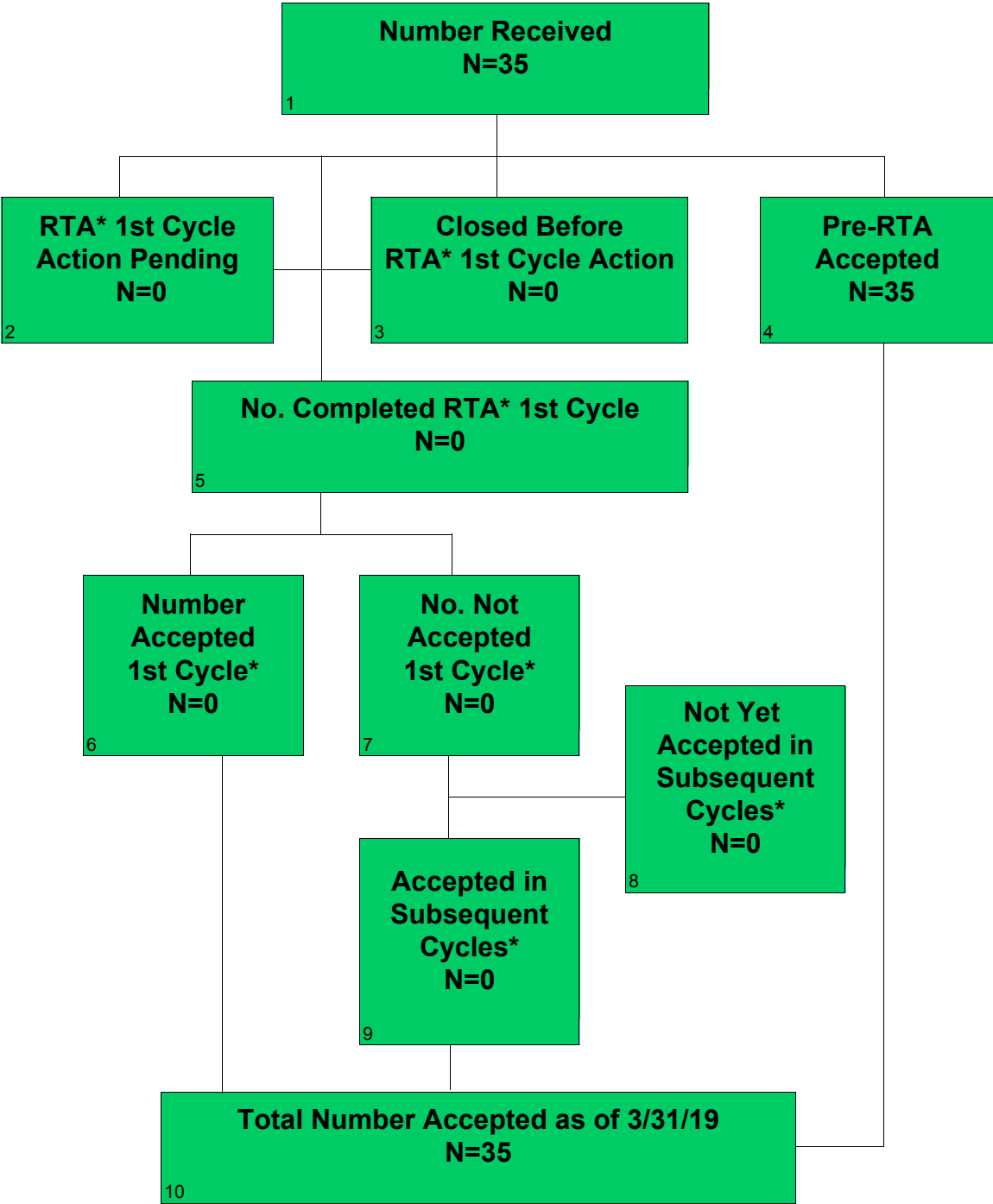
\* RTA was implemented on TBD, thus RTA metrics include only De Novos received on or after TBD. All other tables include De Novos received on or after October 1, 2017.

# CDRH De Novo - FY 2018 as of 3/31/19 Continued

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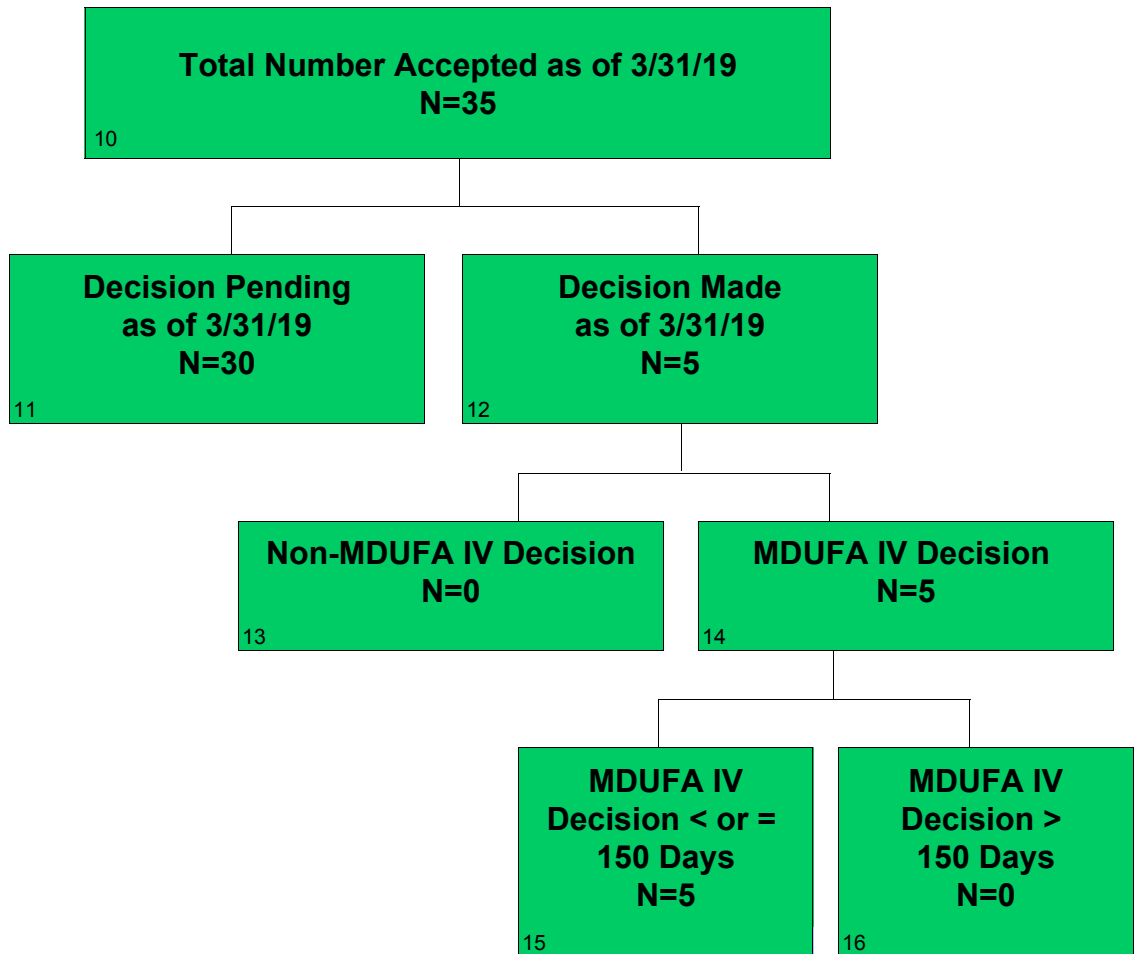
# CDRH De Novo - FY 2019 as of 3/31/19



\* RTA was implemented on TBD, thus RTA metrics include only De Novos received on or after TBD. All other tables include De Novos received on or after October 1, 2017.

# CDRH De Novo - FY 2019 as of 3/31/19 Continued

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## Section 8 De Novo Center Level Metrics

**Table 8.1 CDRH - De Novo Acceptance Review Decision\***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	56	35			
Closed Before RTA Action	N/A	N/A			
Number Accepted First RTA Cycle	N/A	N/A			
Number Without a RTA Review and > 15 Days Since Date Received	N/A	N/A			
Number Without a RTA Review and <= 15 Days Since Date Received	N/A	N/A			
Number Not Accepted	N/A	N/A			
Rate of Submissions Not Accepted for Review	N/A	N/A			

\* RTA was implemented on TBD, thus RTA metrics in table 8.1 include only De Novos received on or after TBD. All other tables include De Novos received on or after October 1, 2017.

**Table 8.2 CDRH - De Novo MDUFA IV Decision Performance Goals**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	50% Within 150 FDA Days	55% Within 150 FDA Days	60% Within 150 FDA Days	65% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	56	35			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	41	5			
MDUFA IV Decisions Within 150 FDA Days	33	5			
De Novos Pending MDUFA IV Decision	15	30			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	2	0			
Current Performance Percent Within 150 FDA Days	76.74%	100%			

**Table 8.3 CDRH - De Novo Time to MDUFA IV Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Average Review Cycles	1.49	1.00			
Number With MDUFA IV Decision	41	5			
<b>Average FDA Days to MDUFA IV Decision</b>	124.98	85.80			
20th Percentile FDA Days to MDUFA IV Decision	75	65			
40th Percentile FDA Days to MDUFA IV Decision	123	76			
60th Percentile FDA Days to MDUFA IV Decision	148	89			
80th Percentile FDA Days to MDUFA IV Decision	150	116			
Maximum FDA Days to MDUFA IV Decision	254	150			
<b>Average Industry Days to MDUFA IV Decision</b>	88.98	0			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	38	0			
60th Percentile Industry Days to MDUFA IV Decision	161	0			
80th Percentile Industry Days to MDUFA IV Decision	177	0			
Maximum Industry Days to MDUFA IV Decision	203	0			
<b>Average Total Days to MDUFA IV Decision</b>	213.95	85.80			
20th Percentile Total Days to MDUFA IV Decision	109	65			
40th Percentile Total Days to MDUFA IV Decision	173	76			
60th Percentile Total Days to MDUFA IV Decision	267	89			
80th Percentile Total Days to MDUFA IV Decision	318	116			
Maximum Total Days to MDUFA IV Decision	371	150			

**Table 8.4 CDRH - De Novo Performance Metrics - Rate of Grant, Decline, Withdrawal and Delete Decisions**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	56	35			
Number With MDUFA IV Decisions	41	5			
Number With Granted Decisions	22	1			
Number With Declined Decisions	8	1			
Number of Withdrawals	7	3			
Number Deleted	4	0			
Rate of Granted Decisions	53.66%	20.00%			
Rate of Declined Decisions	19.51%	20.00%			
Rate of Withdrawals	17.07%	60.00%			
Rate of Deleted	7.14%	0%			

**Table 8.5 CDRH - De Novo Performance Metrics-Submissions Missing Performance Goals**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	8	0			
Mean FDA Days for Submissions that Missed the Goal	188.00	0			
Mean Industry Days for Submissions that Missed the Goal	128.38	0			

**Table 8.6 CDRH - LDT De Novo MDUFA IV Decision Metrics**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	1	1			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	1	1			
MDUFA IV Decisions Within 150 FDA Days	1	1			
De Novos Pending MDUFA IV Decision	0	0			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	100%	100%			

**Table 8.7 CDRH - Conventional IVD (non-LDT) De Novo MDUFA IV Decision Metrics**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	15	8			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	12	2			
MDUFA IV Decisions Within 150 FDA Days	12	2			
De Novos Pending MDUFA IV Decision	3	6			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	100%	100%			

## Section 8 - De Novo Office Level Metrics

Table 8.1 ODE - CDRH - De Novo Acceptance Review Decision\*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	39	26			
Closed Before RTA Action	N/A	N/A			
Number Accepted First RTA Cycle	N/A	N/A			
Number Without a RTA Review and > 15 Days Since Date Received	N/A	N/A			
Number Without a RTA Review and <= 15 Days Since Date Received	N/A	N/A			
Number Not Accepted	N/A	N/A			
Rate of Submissions Not Accepted for Review	N/A	N/A			

\* RTA was implemented on TBD, thus RTA metrics in table 8.1 include only De Novos received on or after TBD. All other tables include De Novos received on or after October 1, 2017.

Table 8.2 ODE - CDRH - De Novo MDUFA IV Decision Performance Goals

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	50% Within 150 FDA Days	55% Within 150 FDA Days	60% Within 150 FDA Days	65% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	39	26			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	27	2			
MDUFA IV Decisions Within 150 FDA Days	19	2			
De Novos Pending MDUFA IV Decision	12	24			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	2	0			
Current Performance Percent Within 150 FDA Days	65.52%	100%			

**Table 8.3 ODE - CDRH - De Novo Time to MDUFA IV Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Average Review Cycles	1.56	1.00			
Number With MDUFA IV Decision	27	2			
<b>Average FDA Days to MDUFA IV Decision</b>	126.96	76.00			
20th Percentile FDA Days to MDUFA IV Decision	67	76			
40th Percentile FDA Days to MDUFA IV Decision	147	76			
60th Percentile FDA Days to MDUFA IV Decision	150	76			
80th Percentile FDA Days to MDUFA IV Decision	153	76			
Maximum FDA Days to MDUFA IV Decision	254	76			
<b>Average Industry Days to MDUFA IV Decision</b>	89.00	0			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	43	0			
60th Percentile Industry Days to MDUFA IV Decision	139	0			
80th Percentile Industry Days to MDUFA IV Decision	176	0			
Maximum Industry Days to MDUFA IV Decision	203	0			
<b>Average Total Days to MDUFA IV Decision</b>	215.96	76.00			
20th Percentile Total Days to MDUFA IV Decision	67	76			
40th Percentile Total Days to MDUFA IV Decision	222	76			
60th Percentile Total Days to MDUFA IV Decision	279	76			
80th Percentile Total Days to MDUFA IV Decision	318	76			
Maximum Total Days to MDUFA IV Decision	371	76			

**Table 8.4 ODE - CDRH - De Novo Performance Metrics - Rate of Grant, Decline, Withdrawal and Delete Decisions**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	39	26			
Number With MDUFA IV Decisions	27	2			
Number With Granted Decisions	13	0			
Number With Declined Decisions	7	1			
Number of Withdrawals	4	1			
Number Deleted	3	0			
Rate of Granted Decisions	48.15%	0%			
Rate of Declined Decisions	25.93%	50.00%			
Rate of Withdrawals	14.81%	50.00%			
Rate of Deleted	7.69%	0%			

**Table 8.5 ODE - CDRH - De Novo Performance Metrics-Submissions Missing Performance Goals**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	8	0			
Mean FDA Days for Submissions That Missed the Goal	188.00	0			
Mean Industry Days for Submissions That Missed the Goal	128.38	0			

**Table 8.6 ODE - CDRH - LDT De Novo MDUFA IV Metrics**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0	0			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	0	0			
MDUFA IV Decisions Within 150 FDA Days	0	0			
De Novos Pending MDUFA IV Decision	0	0			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	N/A	N/A			

**Table 8.7 ODE - CDRH - Conventional IV (non-LDT) De Novo MDUFA IV Decision Metrics**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0	0			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	0	0			
MDUFA IV Decisions Within 150 FDA Days	0	0			
De Novos Pending MDUFA IV Decision	0	0			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	N/A	N/A			

## Section 8 - De Novo Office Level Metrics

Table 8.1 OIR - CDRH - De Novo Acceptance Review Decision\*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	17	9			
Closed Before RTA Action	N/A	N/A			
Number Accepted First RTA Cycle	N/A	N/A			
Number Without a RTA Review and > 15 Days Since Date Received	N/A	N/A			
Number Without a RTA Review and <= 15 Days Since Date Received	N/A	N/A			
Number Not Accepted	N/A	N/A			
Rate of Submissions Not Accepted for Review	N/A	N/A			

\* RTA was implemented on TBD, thus RTA metrics in table 8.1 include only De Novos received on or after TBD. All other tables include De Novos received on or after October 1, 2017.

Table 8.2 OIR - CDRH - De Novo MDUFA IV Decision Performance Goals

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	50% Within 150 FDA Days	55% Within 150 FDA Days	60% Within 150 FDA Days	65% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	17	9			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	14	3			
MDUFA IV Decisions Within 150 FDA Days	14	3			
De Novos Pending MDUFA IV Decision	3	6			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	100%	100%			

**Table 8.3 OIR - CDRH - De Novo Time to MDUFA IV Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Average Review Cycles	1.36	1.00			
Number With MDUFA IV Decision	14	3			
<b>Average FDA Days to MDUFA IV Decision</b>	121.14	92.33			
20th Percentile FDA Days to MDUFA IV Decision	95	55			
40th Percentile FDA Days to MDUFA IV Decision	122	90			
60th Percentile FDA Days to MDUFA IV Decision	142	116			
80th Percentile FDA Days to MDUFA IV Decision	149	133			
Maximum FDA Days to MDUFA IV Decision	150	150			
<b>Average Industry Days to MDUFA IV Decision</b>	88.93	0			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	12	0			
60th Percentile Industry Days to MDUFA IV Decision	153	0			
80th Percentile Industry Days to MDUFA IV Decision	178	0			
Maximum Industry Days to MDUFA IV Decision	189	0			
<b>Average Total Days to MDUFA IV Decision</b>	210.07	92.33			
20th Percentile Total Days to MDUFA IV Decision	130	55			
40th Percentile Total Days to MDUFA IV Decision	147	90			
60th Percentile Total Days to MDUFA IV Decision	248	116			
80th Percentile Total Days to MDUFA IV Decision	307	133			
Maximum Total Days to MDUFA IV Decision	327	150			



**Table 8.4 OIR - CDRH - De Novo Performance Metrics - Rate of Grant, Decline, Withdrawal and Delete Decisions**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	17	9			
Number With MDUFA IV Decisions	14	3			
Number With Granted Decisions	9	1			
Number With Declined Decisions	1	0			
Number of Withdrawals	3	2			
Number Deleted	1	0			
Rate of Granted Decisions	64.29%	33.33%			
Rate of Declined Decisions	7.14%	0%			
Rate of Withdrawals	21.43%	66.67%			
Rate of Deleted	5.88%	0%			

**Table 8.5 OIR - CDRH - De Novo Performance Metrics-Submissions Missing Performance Goals**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions That Missed the Goal	0	0			
Mean Industry Days for Submissions That Missed the Goal	0	0			

**Table 8.6 OIR - CDRH - LDT De Novo MDUFA IV Metrics**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	1	1			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	1	1			
MDUFA IV Decisions Within 150 FDA Days	1	1			
De Novos Pending MDUFA IV Decision	0	0			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	100%	100%			

**Table 8.7 OIR - CDRH - Conventional IV (non-LDT) De Novo MDUFA IV Decision Metrics**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	15	8			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	12	2			
MDUFA IV Decisions Within 150 FDA Days	12	2			
De Novos Pending MDUFA IV Decision	3	6			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	100%	100%			

## Section 8 - De Novo Division Level Metrics

Table 8.1 DAGRID - ODE - CDRH - De Novo Acceptance Review Decision\*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	3	1			
Closed Before RTA Action	N/A	N/A			
Number Accepted First RTA Cycle	N/A	N/A			
Number Without a RTA Review and > 15 Days Since Date Received	N/A	N/A			
Number Without a RTA Review and <= 15 Days Since Date Received	N/A	N/A			
Number Not Accepted	N/A	N/A			
Rate of Submissions Not Accepted for Review	N/A	N/A			

\* RTA was implemented on TBD, thus RTA metrics in table 8.1 include only De Novos received on or after TBD. All other tables include De Novos received on or after October 1, 2017.

Table 8.2 DAGRID - ODE - CDRH - De Novo MDUFA IV Decision Performance Goals

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	50% Within 150 FDA Days	55% Within 150 FDA Days	60% Within 150 FDA Days	65% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	3	1			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	3	0			
MDUFA IV Decisions Within 150 FDA Days	1	0			
De Novos Pending MDUFA IV Decision	0	1			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	33.33%	N/A			

**Table 8.3 DAGRID - ODE - CDRH - De Novo Time to MDUFA IV Decisions**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Average Review Cycles	2.00	0			
Number with MDUFA IV Decision	3	0			
<b>Average FDA Days to MDUFA IV Decision</b>	169.33	0			
20th Percentile FDA Days to MDUFA IV Decision	156	0			
40th Percentile FDA Days to MDUFA IV Decision	161	0			
60th Percentile FDA Days to MDUFA IV Decision	170	0			
80th Percentile FDA Days to MDUFA IV Decision	182	0			
Maximum FDA Days to MDUFA IV Decision	194	0			
<b>Average Industry Days to MDUFA IV Decision</b>	83.67	0			
20th Percentile Industry Days to MDUFA IV Decision	34	0			
40th Percentile Industry Days to MDUFA IV Decision	45	0			
60th Percentile Industry Days to MDUFA IV Decision	76	0			
80th Percentile Industry Days to MDUFA IV Decision	127	0			
Maximum Industry Days to MDUFA IV Decision	177	0			
<b>Average Total Days to MDUFA IV Decision</b>	253.00	0			
20th Percentile Total Days to MDUFA IV Decision	202	0			
40th Percentile Total Days to MDUFA IV Decision	231	0			
60th Percentile Total Days to MDUFA IV Decision	264	0			
80th Percentile Total Days to MDUFA IV Decision	303	0			
Maximum Total Days to MDUFA IV Decision	341	0			

**Table 8.4 DAGRID - ODE - CDRH - De Novo Performance Metrics - Rate of Grant, Decline, Withdrawal and Delete Decisions**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	3	1			
Number with MDUFA IV Decision	3	0			
Number with Granted Decisions	2	0			
Number with Declined Decisions	1	0			
Number of Withdrawals	0	0			
Number Deleted	0	0			
Rate of Granted Decisions	66.67%	N/A			
Rate of Declined Decisions	33.33%	N/A			
Rate of Withdrawals	0%	N/A			
Rate of Deleted	0%	0%			

**Table 8.5 DAGRID - ODE - CDRH - De Novo Performance Metrics-Submissions Missing Perform:**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	2	0			
Mean FDA Days for Submissions that Missed the Goal	179.00	0			
Mean Industry Days for Submissions that Missed the Goal	114.00	0			

**Table 8.6 DAGRID - ODE - CDRH - LDT De Novo MDUFA IV Decision Metrics**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0	0			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	0	0			
MDUFA IV Decisions Within 150 FDA Days	0	0			
De Novos Pending MDUFA IV Decision	0	0			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	N/A	N/A			

**Table 8.7 DAGRID - ODE - CDRH - Conventional IVD (non-LDT) De Novo MDUFA IV Decision Me**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0	0			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	0	0			
MDUFA IV Decisions Within 150 FDA Days	0	0			
De Novos Pending MDUFA IV Decision	0	0			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	N/A	N/A			

## Section 8 - De Novo Division Level Metrics

Table 8.1 DCD - ODE - CDRH - De Novo Acceptance Review Decision\*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	5	6			
Closed Before RTA Action	N/A	N/A			
Number Accepted First RTA Cycle	N/A	N/A			
Number Without a RTA Review and > 15 Days Since Date Received	N/A	N/A			
Number Without a RTA Review and <= 15 Days Since Date Received	N/A	N/A			
Number Not Accepted	N/A	N/A			
Rate of Submissions Not Accepted for Review	N/A	N/A			

\* RTA was implemented on TBD, thus RTA metrics in table 8.1 include only De Novos received on or after TBD. All other tables include De Novos received on or after October 1, 2017.

Table 8.2 DCD - ODE - CDRH - De Novo MDUFA IV Decision Performance Goals

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	50% Within 150 FDA Days	55% Within 150 FDA Days	60% Within 150 FDA Days	65% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	5	6			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	4	0			
MDUFA IV Decisions Within 150 FDA Days	4	0			
De Novos Pending MDUFA IV Decision	1	6			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	100%	N/A			

**Table 8.3 DCD - ODE - CDRH - De Novo Time to MDUFA IV Decisions**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Average Review Cycles	1.25	0			
Number with MDUFA IV Decision	4	0			
<b>Average FDA Days to MDUFA IV Decision</b>	<b>73.75</b>	<b>0</b>			
20th Percentile FDA Days to MDUFA IV Decision	31	0			
40th Percentile FDA Days to MDUFA IV Decision	44	0			
60th Percentile FDA Days to MDUFA IV Decision	75	0			
80th Percentile FDA Days to MDUFA IV Decision	111	0			
Maximum FDA Days to MDUFA IV Decision	148	0			
<b>Average Industry Days to MDUFA IV Decision</b>	<b>86.25</b>	<b>0</b>			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	33	0			
60th Percentile Industry Days to MDUFA IV Decision	131	0			
80th Percentile Industry Days to MDUFA IV Decision	171	0			
Maximum Industry Days to MDUFA IV Decision	181	0			
<b>Average Total Days to MDUFA IV Decision</b>	<b>160.00</b>	<b>0</b>			
20th Percentile Total Days to MDUFA IV Decision	31	0			
40th Percentile Total Days to MDUFA IV Decision	80	0			
60th Percentile Total Days to MDUFA IV Decision	220	0			
80th Percentile Total Days to MDUFA IV Decision	285	0			
Maximum Total Days to MDUFA IV Decision	312	0			

**Table 8.4 DCD - ODE - CDRH - De Novo Performance Metrics - Rate of Grant, Decline, Withdrawal and Delete Decisions**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	5	6			
Number with MDUFA IV Decision	4	0			
Number with Granted Decisions	3	0			
Number with Declined Decisions	0	0			
Number of Withdrawals	0	0			
Number Deleted	1	0			
Rate of Granted Decisions	75.00%	N/A			
Rate of Declined Decisions	0%	N/A			
Rate of Withdrawals	0%	N/A			
Rate of Deleted	20.00%	0%			

**Table 8.5 DCD - ODE - CDRH - De Novo Performance Metrics-Submissions Missing Performance**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 8.6 DCD - ODE - CDRH - LDT De Novo MDUFA IV Decision Metrics**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0	0			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	0	0			
MDUFA IV Decisions Within 150 FDA Days	0	0			
De Novos Pending MDUFA IV Decision	0	0			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	N/A	N/A			

**Table 8.7 DCD - ODE - CDRH - Conventional IVD (non-LDT) De Novo MDUFA IV Decision Metrics**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0	0			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	0	0			
MDUFA IV Decisions Within 150 FDA Days	0	0			
De Novos Pending MDUFA IV Decision	0	0			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	N/A	N/A			

## Section 8 - De Novo Division Level Metrics

Table 8.1 DNPMD - ODE - CDRH - De Novo Acceptance Review Decision\*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	13	5			
Closed Before RTA Action	N/A	N/A			
Number Accepted First RTA Cycle	N/A	N/A			
Number Without a RTA Review and > 15 Days Since Date Received	N/A	N/A			
Number Without a RTA Review and <= 15 Days Since Date Received	N/A	N/A			
Number Not Accepted	N/A	N/A			
Rate of Submissions Not Accepted for Review	N/A	N/A			

\* RTA was implemented on TBD, thus RTA metrics in table 8.1 include only De Novos received on or after TBD. All other tables include De Novos received on or after October 1, 2017.

Table 8.2 DNPMD - ODE - CDRH - De Novo MDUFA IV Decision Performance Goals

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	50% Within 150 FDA Days	55% Within 150 FDA Days	60% Within 150 FDA Days	65% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	13	5			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	6	1			
MDUFA IV Decisions Within 150 FDA Days	3	1			
De Novos Pending MDUFA IV Decision	7	4			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	1	0			
Current Performance Percent Within 150 FDA Days	42.86%	100%			



**Table 8.3 DNPMD - ODE - CDRH - De Novo Time to MDUFA IV Decisions**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Average Review Cycles	1.67	1.00			
Number with MDUFA IV Decision	6	1			
<b>Average FDA Days to MDUFA IV Decision</b>	157.33	76.00			
20th Percentile FDA Days to MDUFA IV Decision	53	76			
40th Percentile FDA Days to MDUFA IV Decision	150	76			
60th Percentile FDA Days to MDUFA IV Decision	208	76			
80th Percentile FDA Days to MDUFA IV Decision	229	76			
Maximum FDA Days to MDUFA IV Decision	254	76			
<b>Average Industry Days to MDUFA IV Decision</b>	77.33	0			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	38	0			
60th Percentile Industry Days to MDUFA IV Decision	89	0			
80th Percentile Industry Days to MDUFA IV Decision	163	0			
Maximum Industry Days to MDUFA IV Decision	174	0			
<b>Average Total Days to MDUFA IV Decision</b>	234.67	76.00			
20th Percentile Total Days to MDUFA IV Decision	53	76			
40th Percentile Total Days to MDUFA IV Decision	292	76			
60th Percentile Total Days to MDUFA IV Decision	318	76			
80th Percentile Total Days to MDUFA IV Decision	324	76			
Maximum Total Days to MDUFA IV Decision	371	76			

**Table 8.4 DNPMD - ODE - CDRH - De Novo Performance Metrics - Rate of Grant, Decline, Withdrawal and Delete Decisions**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	13	5			
Number with MDUFA IV Decision	6	1			
Number with Granted Decisions	2	0			
Number with Declined Decisions	2	0			
Number of Withdrawals	2	1			
Number Deleted	0	0			
Rate of Granted Decisions	33.33%	0%			
Rate of Declined Decisions	33.33%	0%			
Rate of Withdrawals	33.33%	100%			
Rate of Deleted	0%	0%			

**Table 8.5 DNPMD - ODE - CDRH - De Novo Performance Metrics-Submissions Missing Performa**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	3	0			
Mean FDA Days for Submissions that Missed the Goal	230.33	0			
Mean Industry Days for Submissions that Missed the Goal	96.67	0			

**Table 8.6 DNPMD - ODE - CDRH - LDT De Novo MDUFA IV Decision Metrics**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0	0			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	0	0			
MDUFA IV Decisions Within 150 FDA Days	0	0			
De Novos Pending MDUFA IV Decision	0	0			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	N/A	N/A			

**Table 8.7 DNPMD - ODE - CDRH - Conventional IVD (non-LDT) De Novo MDUFA IV Decision Met**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0	0			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	0	0			
MDUFA IV Decisions Within 150 FDA Days	0	0			
De Novos Pending MDUFA IV Decision	0	0			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	N/A	N/A			

## Section 8 - De Novo Division Level Metrics

Table 8.1 DOD - ODE - CDRH - De Novo Acceptance Review Decision\*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	4	4			
Closed Before RTA Action	N/A	N/A			
Number Accepted First RTA Cycle	N/A	N/A			
Number Without a RTA Review and > 15 Days Since Date Received	N/A	N/A			
Number Without a RTA Review and <= 15 Days Since Date Received	N/A	N/A			
Number Not Accepted	N/A	N/A			
Rate of Submissions Not Accepted for Review	N/A	N/A			

\* RTA was implemented on TBD, thus RTA metrics in table 8.1 include only De Novos received on or after TBD. All other tables include De Novos received on or after October 1, 2017.

Table 8.2 DOD - ODE - CDRH - De Novo MDUFA IV Decision Performance Goals

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	50% Within 150 FDA Days	55% Within 150 FDA Days	60% Within 150 FDA Days	65% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	4	4			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	3	0			
MDUFA IV Decisions Within 150 FDA Days	2	0			
De Novos Pending MDUFA IV Decision	1	4			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	66.67%	N/A			

**Table 8.3 DOD - ODE - CDRH - De Novo Time to MDUFA IV Decisions**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Average Review Cycles	1.33	0			
Number with MDUFA IV Decision	3	0			
<b>Average FDA Days to MDUFA IV Decision</b>	127.67	0			
20th Percentile FDA Days to MDUFA IV Decision	110	0			
40th Percentile FDA Days to MDUFA IV Decision	135	0			
60th Percentile FDA Days to MDUFA IV Decision	149	0			
80th Percentile FDA Days to MDUFA IV Decision	150	0			
Maximum FDA Days to MDUFA IV Decision	151	0			
<b>Average Industry Days to MDUFA IV Decision</b>	155.00	0			
20th Percentile Industry Days to MDUFA IV Decision	134	0			
40th Percentile Industry Days to MDUFA IV Decision	165	0			
60th Percentile Industry Days to MDUFA IV Decision	180	0			
80th Percentile Industry Days to MDUFA IV Decision	181	0			
Maximum Industry Days to MDUFA IV Decision	181	0			
<b>Average Total Days to MDUFA IV Decision</b>	282.67	0			
20th Percentile Total Days to MDUFA IV Decision	257	0			
40th Percentile Total Days to MDUFA IV Decision	262	0			
60th Percentile Total Days to MDUFA IV Decision	278	0			
80th Percentile Total Days to MDUFA IV Decision	305	0			
Maximum Total Days to MDUFA IV Decision	331	0			

**Table 8.4 DOD - ODE - CDRH - De Novo Performance Metrics - Rate of Grant, Decline, Withdrawal and Delete Decisions**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	4	4			
Number with MDUFA IV Decision	3	0			
Number with Granted Decisions	1	0			
Number with Declined Decisions	0	0			
Number of Withdrawals	1	0			
Number Deleted	1	0			
Rate of Granted Decisions	33.33%	N/A			
Rate of Declined Decisions	0%	N/A			
Rate of Withdrawals	33.33%	N/A			
Rate of Deleted	25.00%	0%			

**Table 8.5 DOD - ODE - CDRH - De Novo Performance Metrics-Submissions Missing Performance**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	1	0			
Mean FDA Days for Submissions that Missed the Goal	151.00	0			
Mean Industry Days for Submissions that Missed the Goal	180.00	0			

**Table 8.6 DOD - ODE - CDRH - LDT De Novo MDUFA IV Decision Metrics**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0	0			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	0	0			
MDUFA IV Decisions Within 150 FDA Days	0	0			
De Novos Pending MDUFA IV Decision	0	0			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	N/A	N/A			

**Table 8.7 DOD - ODE - CDRH - Conventional IVD (non-LDT) De Novo MDUFA IV Decision Metrics**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0	0			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	0	0			
MDUFA IV Decisions Within 150 FDA Days	0	0			
De Novos Pending MDUFA IV Decision	0	0			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	N/A	N/A			

## Section 8 - De Novo Division Level Metrics

Table 8.1 DOED - ODE - CDRH - De Novo Acceptance Review Decision\*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	5	1			
Closed Before RTA Action	N/A	N/A			
Number Accepted First RTA Cycle	N/A	N/A			
Number Without a RTA Review and > 15 Days Since Date Received	N/A	N/A			
Number Without a RTA Review and <= 15 Days Since Date Received	N/A	N/A			
Number Not Accepted	N/A	N/A			
Rate of Submissions Not Accepted for Review	N/A	N/A			

\* RTA was implemented on TBD, thus RTA metrics in table 8.1 include only De Novos received on or after TBD. All other tables include De Novos received on or after October 1, 2017.

Table 8.2 DOED - ODE - CDRH - De Novo MDUFA IV Decision Performance Goals

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	50% Within 150 FDA Days	55% Within 150 FDA Days	60% Within 150 FDA Days	65% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	5	1			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	3	0			
MDUFA IV Decisions Within 150 FDA Days	3	0			
De Novos Pending MDUFA IV Decision	2	1			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	100%	N/A			

**Table 8.3 DOED - ODE - CDRH - De Novo Time to MDUFA IV Decisions**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Average Review Cycles	1.33	0			
Number with MDUFA IV Decision	3	0			
<b>Average FDA Days to MDUFA IV Decision</b>	127.33	0			
20th Percentile FDA Days to MDUFA IV Decision	110	0			
40th Percentile FDA Days to MDUFA IV Decision	135	0			
60th Percentile FDA Days to MDUFA IV Decision	148	0			
80th Percentile FDA Days to MDUFA IV Decision	149	0			
Maximum FDA Days to MDUFA IV Decision	150	0			
<b>Average Industry Days to MDUFA IV Decision</b>	18.67	0			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	11	0			
80th Percentile Industry Days to MDUFA IV Decision	34	0			
Maximum Industry Days to MDUFA IV Decision	56	0			
<b>Average Total Days to MDUFA IV Decision</b>	146.00	0			
20th Percentile Total Days to MDUFA IV Decision	110	0			
40th Percentile Total Days to MDUFA IV Decision	135	0			
60th Percentile Total Days to MDUFA IV Decision	159	0			
80th Percentile Total Days to MDUFA IV Decision	182	0			
Maximum Total Days to MDUFA IV Decision	206	0			

**Table 8.4 DOED - ODE - CDRH - De Novo Performance Metrics - Rate of Grant, Decline, Withdrawal and Delete Decisions**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	5	1			
Number with MDUFA IV Decision	3	0			
Number with Granted Decisions	3	0			
Number with Declined Decisions	0	0			
Number of Withdrawals	0	0			
Number Deleted	0	0			
Rate of Granted Decisions	100%	N/A			
Rate of Declined Decisions	0%	N/A			
Rate of Withdrawals	0%	N/A			
Rate of Deleted	0%	0%			

**Table 8.5 DOED - ODE - CDRH - De Novo Performance Metrics-Submissions Missing Performan**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 8.6 DOED - ODE - CDRH - LDT De Novo MDUFA IV Decision Metrics**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0	0			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	0	0			
MDUFA IV Decisions Within 150 FDA Days	0	0			
De Novos Pending MDUFA IV Decision	0	0			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	N/A	N/A			

**Table 8.7 DOED - ODE - CDRH - Conventional IVD (non-LDT) De Novo MDUFA IV Decision Metric**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0	0			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	0	0			
MDUFA IV Decisions Within 150 FDA Days	0	0			
De Novos Pending MDUFA IV Decision	0	0			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	N/A	N/A			



## Section 8 - De Novo Division Level Metrics

Table 8.1 DRGUD - ODE - CDRH - De Novo Acceptance Review Decision\*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	4	6			
Closed Before RTA Action	N/A	N/A			
Number Accepted First RTA Cycle	N/A	N/A			
Number Without a RTA Review and > 15 Days Since Date Received	N/A	N/A			
Number Without a RTA Review and <= 15 Days Since Date Received	N/A	N/A			
Number Not Accepted	N/A	N/A			
Rate of Submissions Not Accepted for Review	N/A	N/A			

\* RTA was implemented on TBD, thus RTA metrics in table 8.1 include only De Novos received on or after TBD. All other tables include De Novos received on or after October 1, 2017.

Table 8.2 DRGUD - ODE - CDRH - De Novo MDUFA IV Decision Performance Goals

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	50% Within 150 FDA Days	55% Within 150 FDA Days	60% Within 150 FDA Days	65% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	4	6			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	4	0			
MDUFA IV Decisions Within 150 FDA Days	3	0			
De Novos Pending MDUFA IV Decision	0	6			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	75.00%	N/A			

**Table 8.3 DRGUD - ODE - CDRH - De Novo Time to MDUFA IV Decisions**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Average Review Cycles	1.50	0			
Number with MDUFA IV Decision	4	0			
<b>Average FDA Days to MDUFA IV Decision</b>	100.00	0			
20th Percentile FDA Days to MDUFA IV Decision	57	0			
40th Percentile FDA Days to MDUFA IV Decision	97	0			
60th Percentile FDA Days to MDUFA IV Decision	135	0			
80th Percentile FDA Days to MDUFA IV Decision	149	0			
Maximum FDA Days to MDUFA IV Decision	151	0			
<b>Average Industry Days to MDUFA IV Decision</b>	136.75	0			
20th Percentile Industry Days to MDUFA IV Decision	100	0			
40th Percentile Industry Days to MDUFA IV Decision	169	0			
60th Percentile Industry Days to MDUFA IV Decision	175	0			
80th Percentile Industry Days to MDUFA IV Decision	187	0			
Maximum Industry Days to MDUFA IV Decision	203	0			
<b>Average Total Days to MDUFA IV Decision</b>	236.75	0			
20th Percentile Total Days to MDUFA IV Decision	179	0			
40th Percentile Total Days to MDUFA IV Decision	293	0			
60th Percentile Total Days to MDUFA IV Decision	312	0			
80th Percentile Total Days to MDUFA IV Decision	321	0			
Maximum Total Days to MDUFA IV Decision	325	0			

**Table 8.4 DRGUD - ODE - CDRH - De Novo Performance Metrics - Rate of Grant, Decline, Withdrawal and Delete Decisions**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	4	6			
Number with MDUFA IV Decision	4	0			
Number with Granted Decisions	0	0			
Number with Declined Decisions	3	0			
Number of Withdrawals	0	0			
Number Deleted	1	0			
Rate of Granted Decisions	0%	N/A			
Rate of Declined Decisions	75.00%	N/A			
Rate of Withdrawals	0%	N/A			
Rate of Deleted	25.00%	0%			

**Table 8.5 DRGUD - ODE - CDRH - De Novo Performance Metrics-Submissions Missing Performa**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	1	0			
Mean FDA Days for Submissions that Missed the Goal	151.00	0			
Mean Industry Days for Submissions that Missed the Goal	167.00	0			

**Table 8.6 DRGUD - ODE - CDRH - LDT De Novo MDUFA IV Decision Metrics**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0	0			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	0	0			
MDUFA IV Decisions Within 150 FDA Days	0	0			
De Novos Pending MDUFA IV Decision	0	0			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	N/A	N/A			

**Table 8.7 DRGUD - ODE - CDRH - Conventional IVD (non-LDT) De Novo MDUFA IV Decision Met**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0	0			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	0	0			
MDUFA IV Decisions Within 150 FDA Days	0	0			
De Novos Pending MDUFA IV Decision	0	0			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	N/A	N/A			

## Section 8 - De Novo Division Level Metrics

Table 8.1 DSD - ODE - CDRH - De Novo Acceptance Review Decision\*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	5	3			
Closed Before RTA Action	N/A	N/A			
Number Accepted First RTA Cycle	N/A	N/A			
Number Without a RTA Review and > 15 Days Since Date Received	N/A	N/A			
Number Without a RTA Review and <= 15 Days Since Date Received	N/A	N/A			
Number Not Accepted	N/A	N/A			
Rate of Submissions Not Accepted for Review	N/A	N/A			

\* RTA was implemented on TBD, thus RTA metrics in table 8.1 include only De Novos received on or after TBD. All other tables include De Novos received on or after October 1, 2017.

Table 8.2 DSD - ODE - CDRH - De Novo MDUFA IV Decision Performance Goals

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	50% Within 150 FDA Days	55% Within 150 FDA Days	60% Within 150 FDA Days	65% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	5	3			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	4	1			
MDUFA IV Decisions Within 150 FDA Days	3	1			
De Novos Pending MDUFA IV Decision	1	2			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	1	0			
Current Performance Percent Within 150 FDA Days	60.00%	100%			

**Table 8.3 DSD - ODE - CDRH - De Novo Time to MDUFA IV Decisions**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Average Review Cycles	1.75	1.00			
Number with MDUFA IV Decision	4	1			
<b>Average FDA Days to MDUFA IV Decision</b>	129.00	76.00			
20th Percentile FDA Days to MDUFA IV Decision	115	76			
40th Percentile FDA Days to MDUFA IV Decision	150	76			
60th Percentile FDA Days to MDUFA IV Decision	150	76			
80th Percentile FDA Days to MDUFA IV Decision	151	76			
Maximum FDA Days to MDUFA IV Decision	153	76			
<b>Average Industry Days to MDUFA IV Decision</b>	68.75	0			
20th Percentile Industry Days to MDUFA IV Decision	9	0			
40th Percentile Industry Days to MDUFA IV Decision	32	0			
60th Percentile Industry Days to MDUFA IV Decision	81	0			
80th Percentile Industry Days to MDUFA IV Decision	124	0			
Maximum Industry Days to MDUFA IV Decision	162	0			
<b>Average Total Days to MDUFA IV Decision</b>	197.75	76.00			
20th Percentile Total Days to MDUFA IV Decision	124	76			
40th Percentile Total Days to MDUFA IV Decision	182	76			
60th Percentile Total Days to MDUFA IV Decision	231	76			
80th Percentile Total Days to MDUFA IV Decision	275	76			
Maximum Total Days to MDUFA IV Decision	315	76			

**Table 8.4 DSD - ODE - CDRH - De Novo Performance Metrics - Rate of Grant, Decline, Withdrawal and Delete Decisions**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	5	3			
Number with MDUFA IV Decision	4	1			
Number with Granted Decisions	2	0			
Number with Declined Decisions	1	1			
Number of Withdrawals	1	0			
Number Deleted	0	0			
Rate of Granted Decisions	50.00%	0%			
Rate of Declined Decisions	25.00%	100%			
Rate of Withdrawals	25.00%	0%			
Rate of Deleted	0%	0%			

**Table 8.5 DSD - ODE - CDRH - De Novo Performance Metrics-Submissions Missing Performance**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	1	0			
Mean FDA Days for Submissions that Missed the Goal	153.00	0			
Mean Industry Days for Submissions that Missed the Goal	162.00	0			

**Table 8.6 DSD - ODE - CDRH - LDT De Novo MDUFA IV Decision Metrics**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0	0			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	0	0			
MDUFA IV Decisions Within 150 FDA Days	0	0			
De Novos Pending MDUFA IV Decision	0	0			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	N/A	N/A			

**Table 8.7 DSD - ODE - CDRH - Conventional IVD (non-LDT) De Novo MDUFA IV Decision Metrics**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0	0			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	0	0			
MDUFA IV Decisions Within 150 FDA Days	0	0			
De Novos Pending MDUFA IV Decision	0	0			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	N/A	N/A			

## Section 8 - De Novo Division Level Metrics

Table 8.1 DCTD - OIR - CDRH - De Novo Acceptance Review Decision\*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	7	4			
Closed Before RTA Action	N/A	N/A			
Number Accepted First RTA Cycle	N/A	N/A			
Number Without a RTA Review and > 15 Days Since Date Received	N/A	N/A			
Number Without a RTA Review and <= 15 Days Since Date Received	N/A	N/A			
Number Not Accepted	N/A	N/A			
Rate of Submissions Not Accepted for Review	N/A	N/A			

\* RTA was implemented on TBD, thus RTA metrics in table 8.1 include only De Novos received on or after TBD. All other tables include De Novos received on or after October 1, 2017.

Table 8.2 DCTD - OIR - CDRH - De Novo MDUFA IV Decision Performance Goals

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	50% Within 150 FDA Days	55% Within 150 FDA Days	60% Within 150 FDA Days	65% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	7	4			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	6	2			
MDUFA IV Decisions Within 150 FDA Days	6	2			
De Novos Pending MDUFA IV Decision	1	2			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	100%	100%			

**Table 8.3 DCTD - OIR - CDRH - De Novo Time to MDUFA IV Decisions**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Average Review Cycles	1.50	1.00			
Number with MDUFA IV Decision	6	2			
<b>Average FDA Days to MDUFA IV Decision</b>	134.67	129.00			
20th Percentile FDA Days to MDUFA IV Decision	122	116			
40th Percentile FDA Days to MDUFA IV Decision	132	125			
60th Percentile FDA Days to MDUFA IV Decision	147	133			
80th Percentile FDA Days to MDUFA IV Decision	148	142			
Maximum FDA Days to MDUFA IV Decision	150	150			
<b>Average Industry Days to MDUFA IV Decision</b>	80.33	0			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	121	0			
80th Percentile Industry Days to MDUFA IV Decision	180	0			
Maximum Industry Days to MDUFA IV Decision	181	0			
<b>Average Total Days to MDUFA IV Decision</b>	215.00	129.00			
20th Percentile Total Days to MDUFA IV Decision	147	116			
40th Percentile Total Days to MDUFA IV Decision	148	125			
60th Percentile Total Days to MDUFA IV Decision	271	133			
80th Percentile Total Days to MDUFA IV Decision	303	142			
Maximum Total Days to MDUFA IV Decision	312	150			



**Table 8.4 DCTD - OIR - CDRH - De Novo Performance Metrics - Rate of Grant, Decline, Withdrawal and Delete Decisions**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	7	4			
Number with MDUFA IV Decision	6	2			
Number with Granted Decisions	5	1			
Number with Declined Decisions	0	0			
Number of Withdrawals	1	1			
Number Deleted	0	0			
Rate of Granted Decisions	83.33%	50.00%			
Rate of Declined Decisions	0%	0%			
Rate of Withdrawals	16.67%	50.00%			
Rate of Deleted	0%	0%			

**Table 8.5 DCTD - OIR - CDRH - De Novo Performance Metrics-Submissions Missing Performance**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 8.6 DCTD - OIR - CDRH - LDT De Novo MDUFA IV Decision Metrics**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0	0			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	0	0			
MDUFA IV Decisions Within 150 FDA Days	0	0			
De Novos Pending MDUFA IV Decision	0	0			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	N/A	N/A			

**Table 8.7 DCTD - OIR - CDRH - Conventional IVD (non-LDT) De Novo MDUFA IV Decision Metrics**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	7	4			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	6	2			
MDUFA IV Decisions Within 150 FDA Days	6	2			
De Novos Pending MDUFA IV Decision	1	2			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	100%	100%			

## Section 8 - De Novo Division Level Metrics

Table 8.1 DIHD - OIR - CDRH - De Novo Acceptance Review Decision\*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	3	0			
Closed Before RTA Action	N/A	N/A			
Number Accepted First RTA Cycle	N/A	N/A			
Number Without a RTA Review and > 15 Days Since Date Received	N/A	N/A			
Number Without a RTA Review and <= 15 Days Since Date Received	N/A	N/A			
Number Not Accepted	N/A	N/A			
Rate of Submissions Not Accepted for Review	N/A	N/A			

\* RTA was implemented on TBD, thus RTA metrics in table 8.1 include only De Novos received on or after TBD. All other tables include De Novos received on or after October 1, 2017.

Table 8.2 DIHD - OIR - CDRH - De Novo MDUFA IV Decision Performance Goals

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	50% Within 150 FDA Days	55% Within 150 FDA Days	60% Within 150 FDA Days	65% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	3	0			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	2	0			
MDUFA IV Decisions Within 150 FDA Days	2	0			
De Novos Pending MDUFA IV Decision	1	0			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	100%	N/A			

**Table 8.3 DIHD - OIR - CDRH - De Novo Time to MDUFA IV Decisions**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Average Review Cycles	1.50	0			
Number with MDUFA IV Decision	2	0			
<b>Average FDA Days to MDUFA IV Decision</b>	112.50	0			
20th Percentile FDA Days to MDUFA IV Decision	90	0			
40th Percentile FDA Days to MDUFA IV Decision	105	0			
60th Percentile FDA Days to MDUFA IV Decision	120	0			
80th Percentile FDA Days to MDUFA IV Decision	135	0			
Maximum FDA Days to MDUFA IV Decision	150	0			
<b>Average Industry Days to MDUFA IV Decision</b>	168.50	0			
20th Percentile Industry Days to MDUFA IV Decision	164	0			
40th Percentile Industry Days to MDUFA IV Decision	167	0			
60th Percentile Industry Days to MDUFA IV Decision	170	0			
80th Percentile Industry Days to MDUFA IV Decision	173	0			
Maximum Industry Days to MDUFA IV Decision	176	0			
<b>Average Total Days to MDUFA IV Decision</b>	281.00	0			
20th Percentile Total Days to MDUFA IV Decision	254	0			
40th Percentile Total Days to MDUFA IV Decision	272	0			
60th Percentile Total Days to MDUFA IV Decision	290	0			
80th Percentile Total Days to MDUFA IV Decision	308	0			
Maximum Total Days to MDUFA IV Decision	326	0			

**Table 8.4 DIHD - OIR - CDRH - De Novo Performance Metrics - Rate of Grant, Decline, Withdrawal and Delete Decisions**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	3	0			
Number with MDUFA IV Decision	2	0			
Number with Granted Decisions	1	0			
Number with Declined Decisions	0	0			
Number of Withdrawals	1	0			
Number Deleted	0	0			
Rate of Granted Decisions	50.00%	N/A			
Rate of Declined Decisions	0%	N/A			
Rate of Withdrawals	50.00%	N/A			
Rate of Deleted	0%	N/A			

**Table 8.5 DIHD - OIR - CDRH - De Novo Performance Metrics-Submissions Missing Performance**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 8.6 DIHD - OIR - CDRH - LDT De Novo MDUFA IV Decision Metrics**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0	0			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	0	0			
MDUFA IV Decisions Within 150 FDA Days	0	0			
De Novos Pending MDUFA IV Decision	0	0			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	N/A	N/A			

**Table 8.7 DIHD - OIR - CDRH - Conventional IVD (non-LDT) De Novo MDUFA IV Decision Metrics**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	3	0			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	2	0			
MDUFA IV Decisions Within 150 FDA Days	2	0			
De Novos Pending MDUFA IV Decision	1	0			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	100%	N/A			

## Section 8 - De Novo Division Level Metrics

Table 8.1 DMD - OIR - CDRH - De Novo Acceptance Review Decision\*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	5	2			
Closed Before RTA Action	N/A	N/A			
Number Accepted First RTA Cycle	N/A	N/A			
Number Without a RTA Review and > 15 Days Since Date Received	N/A	N/A			
Number Without a RTA Review and <= 15 Days Since Date Received	N/A	N/A			
Number Not Accepted	N/A	N/A			
Rate of Submissions Not Accepted for Review	N/A	N/A			

\* RTA was implemented on TBD, thus RTA metrics in table 8.1 include only De Novos received on or after TBD. All other tables include De Novos received on or after October 1, 2017.

Table 8.2 DMD - OIR - CDRH - De Novo MDUFA IV Decision Performance Goals

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	50% Within 150 FDA Days	55% Within 150 FDA Days	60% Within 150 FDA Days	65% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	5	2			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	4	0			
MDUFA IV Decisions Within 150 FDA Days	4	0			
De Novos Pending MDUFA IV Decision	1	2			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	100%	N/A			

**Table 8.3 DMD - OIR - CDRH - De Novo Time to MDUFA IV Decisions**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Average Review Cycles	1.25	0			
Number with MDUFA IV Decision	4	0			
<b>Average FDA Days to MDUFA IV Decision</b>	123.25	0			
20th Percentile FDA Days to MDUFA IV Decision	104	0			
40th Percentile FDA Days to MDUFA IV Decision	127	0			
60th Percentile FDA Days to MDUFA IV Decision	141	0			
80th Percentile FDA Days to MDUFA IV Decision	147	0			
Maximum FDA Days to MDUFA IV Decision	150	0			
<b>Average Industry Days to MDUFA IV Decision</b>	59.25	0			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	12	0			
60th Percentile Industry Days to MDUFA IV Decision	48	0			
80th Percentile Industry Days to MDUFA IV Decision	107	0			
Maximum Industry Days to MDUFA IV Decision	177	0			
<b>Average Total Days to MDUFA IV Decision</b>	182.50	0			
20th Percentile Total Days to MDUFA IV Decision	130	0			
40th Percentile Total Days to MDUFA IV Decision	137	0			
60th Percentile Total Days to MDUFA IV Decision	143	0			
80th Percentile Total Days to MDUFA IV Decision	218	0			
Maximum Total Days to MDUFA IV Decision	327	0			

**Table 8.4 DMD - OIR - CDRH - De Novo Performance Metrics - Rate of Grant, Decline, Withdrawal and Delete Decisions**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	5	2			
Number with MDUFA IV Decision	4	0			
Number with Granted Decisions	2	0			
Number with Declined Decisions	1	0			
Number of Withdrawals	1	0			
Number Deleted	0	0			
Rate of Granted Decisions	50.00%	N/A			
Rate of Declined Decisions	25.00%	N/A			
Rate of Withdrawals	25.00%	N/A			
Rate of Deleted	0%	0%			

**Table 8.5 DMD - OIR - CDRH - De Novo Performance Metrics-Submissions Missing Performance**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 8.6 DMD - OIR - CDRH - LDT De Novo MDUFA IV Decision Metrics**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0	0			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	0	0			
MDUFA IV Decisions Within 150 FDA Days	0	0			
De Novos Pending MDUFA IV Decision	0	0			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	N/A	N/A			

**Table 8.7 DMD - OIR - CDRH - Conventional IVD (non-LDT) De Novo MDUFA IV Decision Metrics**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	5	2			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	4	0			
MDUFA IV Decisions Within 150 FDA Days	4	0			
De Novos Pending MDUFA IV Decision	1	2			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	100%	N/A			

## Section 8 - De Novo Division Level Metrics

Table 8.1 DMGP - OIR - CDRH - De Novo Acceptance Review Decision\*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	1	3			
Closed Before RTA Action	N/A	N/A			
Number Accepted First RTA Cycle	N/A	N/A			
Number Without a RTA Review and > 15 Days Since Date Received	N/A	N/A			
Number Without a RTA Review and <= 15 Days Since Date Received	N/A	N/A			
Number Not Accepted	N/A	N/A			
Rate of Submissions Not Accepted for Review	N/A	N/A			

\* RTA was implemented on TBD, thus RTA metrics in table 8.1 include only De Novos received on or after TBD. All other tables include De Novos received on or after October 1, 2017.

Table 8.2 DMGP - OIR - CDRH - De Novo MDUFA IV Decision Performance Goals

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	50% Within 150 FDA Days	55% Within 150 FDA Days	60% Within 150 FDA Days	65% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	1	3			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	1	1			
MDUFA IV Decisions Within 150 FDA Days	1	1			
De Novos Pending MDUFA IV Decision	0	2			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	100%	100%			



**Table 8.3 DMGP - OIR - CDRH - De Novo Time to MDUFA IV Decisions**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Average Review Cycles	1.00	1.00			
Number with MDUFA IV Decision	1	1			
<b>Average FDA Days to MDUFA IV Decision</b>	62.00	19.00			
20th Percentile FDA Days to MDUFA IV Decision	62	19			
40th Percentile FDA Days to MDUFA IV Decision	62	19			
60th Percentile FDA Days to MDUFA IV Decision	62	19			
80th Percentile FDA Days to MDUFA IV Decision	62	19			
Maximum FDA Days to MDUFA IV Decision	62	19			
<b>Average Industry Days to MDUFA IV Decision</b>	189.00	0			
20th Percentile Industry Days to MDUFA IV Decision	189	0			
40th Percentile Industry Days to MDUFA IV Decision	189	0			
60th Percentile Industry Days to MDUFA IV Decision	189	0			
80th Percentile Industry Days to MDUFA IV Decision	189	0			
Maximum Industry Days to MDUFA IV Decision	189	0			
<b>Average Total Days to MDUFA IV Decision</b>	251.00	19.00			
20th Percentile Total Days to MDUFA IV Decision	251	19			
40th Percentile Total Days to MDUFA IV Decision	251	19			
60th Percentile Total Days to MDUFA IV Decision	251	19			
80th Percentile Total Days to MDUFA IV Decision	251	19			
Maximum Total Days to MDUFA IV Decision	251	19			

**Table 8.4 DMGP - OIR - CDRH - De Novo Performance Metrics - Rate of Grant, Decline, Withdrawal and Delete Decisions**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	1	3			
Number with MDUFA IV Decision	1	1			
Number with Granted Decisions	0	0			
Number with Declined Decisions	0	0			
Number of Withdrawals	0	1			
Number Deleted	1	0			
Rate of Granted Decisions	0%	0%			
Rate of Declined Decisions	0%	0%			
Rate of Withdrawals	0%	100%			
Rate of Deleted	100%	0%			

**Table 8.5 DMGP - OIR - CDRH - De Novo Performance Metrics-Submissions Missing Performance**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 8.6 DMGP - OIR - CDRH - LDT De Novo MDUFA IV Decision Metrics**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	1	1			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	1	1			
MDUFA IV Decisions Within 150 FDA Days	1	1			
De Novos Pending MDUFA IV Decision	0	0			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	100%	100%			

**Table 8.7 DMGP - OIR - CDRH - Conventional IVD (non-LDT) De Novo MDUFA IV Decision Metric**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0	2			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	0	0			
MDUFA IV Decisions Within 150 FDA Days	0	0			
De Novos Pending MDUFA IV Decision	0	2			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	N/A	N/A			

## Section 8 - De Novo Division Level Metrics

Table 8.1 DRH - OIR - CDRH - De Novo Acceptance Review Decision\*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	1	0			
Closed Before RTA Action	N/A	N/A			
Number Accepted First RTA Cycle	N/A	N/A			
Number Without a RTA Review and > 15 Days Since Date Received	N/A	N/A			
Number Without a RTA Review and <= 15 Days Since Date Received	N/A	N/A			
Number Not Accepted	N/A	N/A			
Rate of Submissions Not Accepted for Review	N/A	N/A			

\* RTA was implemented on TBD, thus RTA metrics in table 8.1 include only De Novos received on or after TBD. All other tables include De Novos received on or after October 1, 2017.

Table 8.2 DRH - OIR - CDRH - De Novo MDUFA IV Decision Performance Goals

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	50% Within 150 FDA Days	55% Within 150 FDA Days	60% Within 150 FDA Days	65% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	1	0			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	1	0			
MDUFA IV Decisions Within 150 FDA Days	1	0			
De Novos Pending MDUFA IV Decision	0	0			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	100%	N/A			

**Table 8.3 DRH - OIR - CDRH - De Novo Time to MDUFA IV Decisions**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Average Review Cycles	1.00	0			
Number with MDUFA IV Decision	1	0			
<b>Average FDA Days to MDUFA IV Decision</b>	108.00	0			
20th Percentile FDA Days to MDUFA IV Decision	108	0			
40th Percentile FDA Days to MDUFA IV Decision	108	0			
60th Percentile FDA Days to MDUFA IV Decision	108	0			
80th Percentile FDA Days to MDUFA IV Decision	108	0			
Maximum FDA Days to MDUFA IV Decision	108	0			
<b>Average Industry Days to MDUFA IV Decision</b>	0	0			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	0	0			
80th Percentile Industry Days to MDUFA IV Decision	0	0			
Maximum Industry Days to MDUFA IV Decision	0	0			
<b>Average Total Days to MDUFA IV Decision</b>	108.00	0			
20th Percentile Total Days to MDUFA IV Decision	108	0			
40th Percentile Total Days to MDUFA IV Decision	108	0			
60th Percentile Total Days to MDUFA IV Decision	108	0			
80th Percentile Total Days to MDUFA IV Decision	108	0			
Maximum Total Days to MDUFA IV Decision	108	0			

**Table 8.4 DRH - OIR - CDRH - De Novo Performance Metrics - Rate of Grant, Decline, Withdrawal and Delete Decisions**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	1	0			
Number with MDUFA IV Decision	1	0			
Number with Granted Decisions	1	0			
Number with Declined Decisions	0	0			
Number of Withdrawals	0	0			
Number Deleted	0	0			
Rate of Granted Decisions	100%	N/A			
Rate of Declined Decisions	0%	N/A			
Rate of Withdrawals	0%	N/A			
Rate of Deleted	0%	N/A			

**Table 8.5 DRH - OIR - CDRH - De Novo Performance Metrics-Submissions Missing Performance**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 8.6 DRH - OIR - CDRH - LDT De Novo MDUFA IV Decision Metrics**

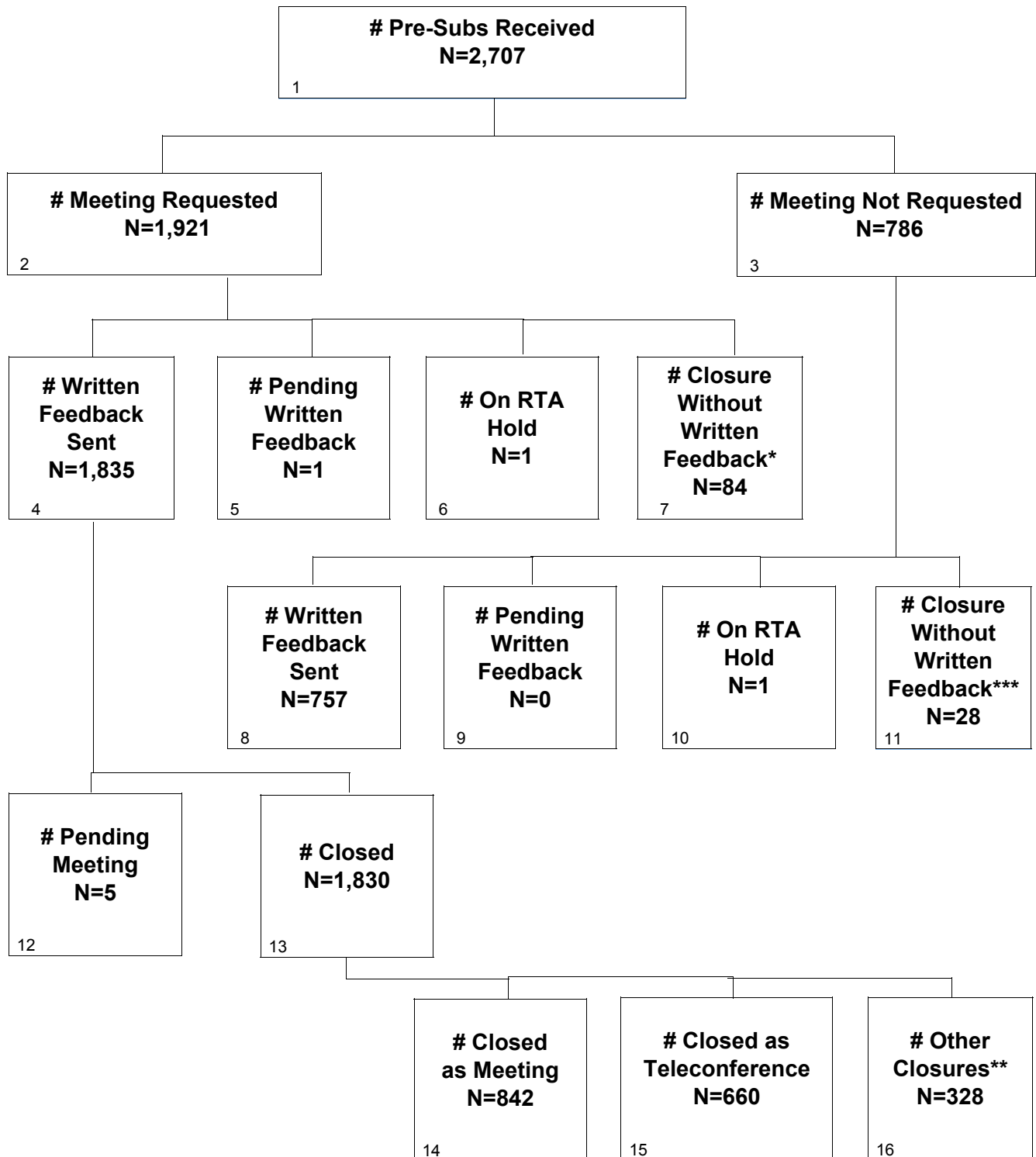
Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0	0			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	0	0			
MDUFA IV Decisions Within 150 FDA Days	0	0			
De Novos Pending MDUFA IV Decision	0	0			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	N/A	N/A			

**Table 8.7 DRH - OIR - CDRH - Conventional IVD (non-LDT) De Novo MDUFA IV Decision Metrics**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0	0			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	0	0			
MDUFA IV Decisions Within 150 FDA Days	0	0			
De Novos Pending MDUFA IV Decision	0	0			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	N/A	N/A			

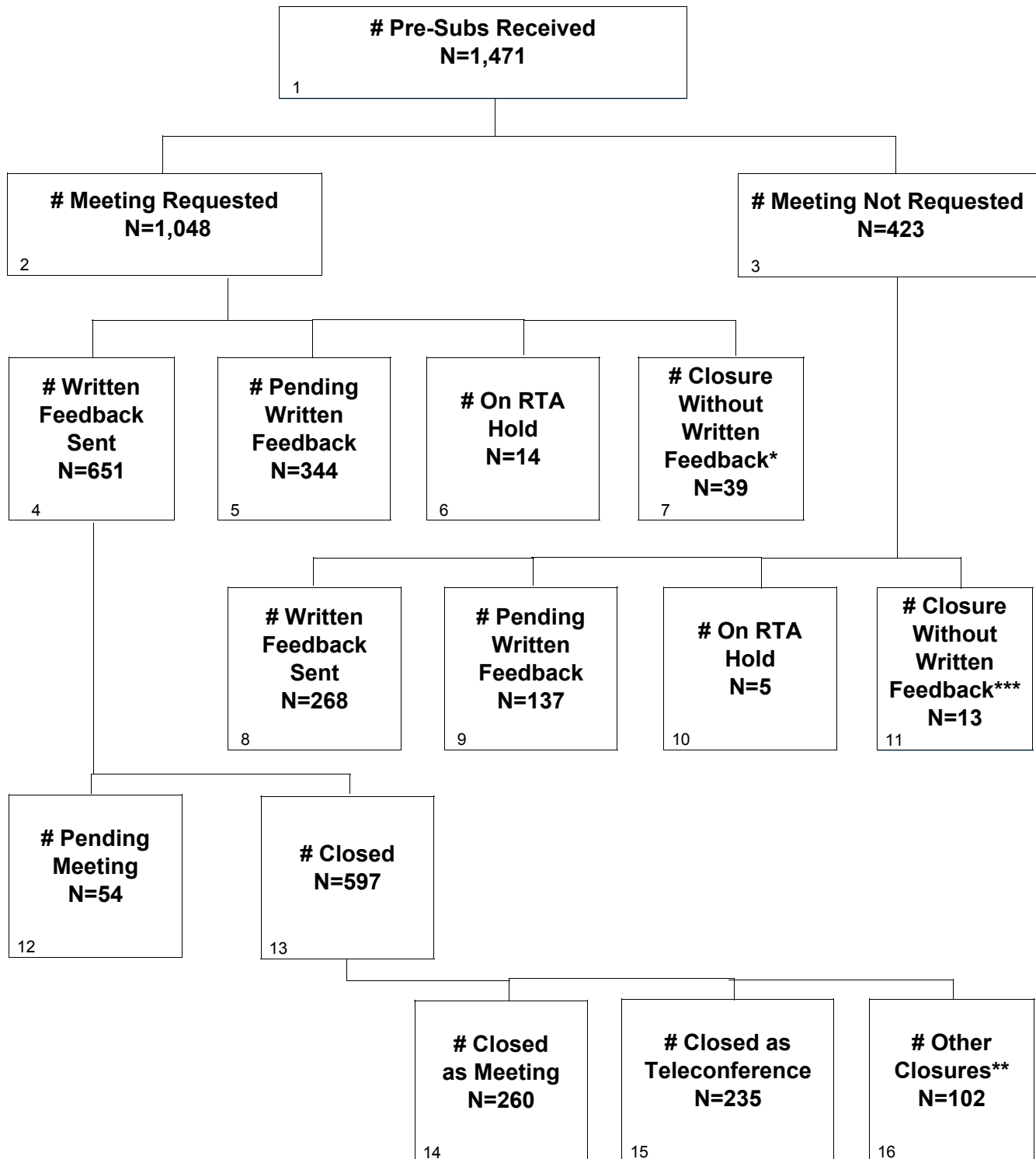
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# CDRH Pre-Sub - FY 2018 as of 3/31/19



\* Closures include TCON, MTNG, CNLR, CNLF, JTRX, JPND, DELE & WTDR  
 \*\* Closures include CNLR, CNLF, JTRX, JPND, DELE & WTDR  
 \*\*\* Closures include JTRX, JPND, DELE & WTDR

# CDRH Pre-Sub - FY 2019 as of 3/31/19



\* Closures include TCON, MTNG, CNLR, CNLF, JTRX, JPND, DELE & WTDR  
 \*\* Closures include CNLR, CNLF, JTRX, JPND, DELE & WTDR  
 \*\*\* Closures include JTRX, JPND, DELE & WTDR



## Section 9 Pre-Sub Center Level Metrics

**Table 9.1 CDRH - Pre-Sub Acceptance Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	2,707	1,471			
Closed Before RTA Action	27	20			
Number Accepted First RTA Cycle	2,565	1,312			
Number Without a RTA Review and > 15 Days Since Date Received	49	24			
Number Without a RTA Review and <= 15 Days Since Date Received	0	84			
Number Not Accepted	66	31			
Rate of Submissions Not Accepted for Review	2.46%	2.27%			

**Table 9.2 CDRH - MDUFA IV Pre-Sub Performance Goals**

Performance Metric	MDUFA IV Goal (# of Submissions Received During FY with Written Feedback Provided by Day 70 or 5 Days Prior to Meeting)				
	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	≥ 1530 Submissions	≥ 1645 Submissions	≥ 1765 Submissions	≥ 1880 Submissions	≥ 1950 Submissions
Written Feedback Sent	2,593	919			
Written Feedback Provided Within MDUFA IV Goal	2,438	867			

**Table 9.3 CDRH - Pre-Sub Time to MDUFA IV Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	2,593	919			
Average FDA Days to Written Feedback	58.86	57.51			
20th Percentile FDA Days to Written Feedback	49	45			
40th Percentile FDA Days to Written Feedback	59	57			
60th Percentile FDA Days to Written Feedback	65	64			
80th Percentile FDA Days to Written Feedback	69	69			
Maximum FDA Days to Written Feedback	172	131			

**Table 9.4 CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Scheduling**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meetings Not Scheduled By Day 30	37	19			
Average Days to Scheduling for Meetings Scheduled After Day 30	35.59	35.32			

**Table 9.5 CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Minutes**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Meeting Held	1,502	495			
Meeting Minutes Submitted Within 15 Days of Meeting	971	285			
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	43			
Meeting Minutes Past 15 Days of Meeting	476	133			
Meeting Minutes Not Submitted and >15 Days Since Meeting	55	34			
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	64.65%	63.05%			

## Section 9 Pre-Sub Office Level Metrics

**Table 9.1 ODE - CDRH - Pre-Sub Acceptance Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	1,822	954			
Closed Before RTA Action	19	16			
Number Accepted First RTA Cycle	1,696	830			
Number Without a RTA Review and > 15 Days Since Date Received	49	20			
Number Without a RTA Review and <= 15 Days Since Date Received	0	62			
Number Not Accepted	58	26			
Rate of Submissions Not Accepted for Review	3.22%	2.97%			

**Table 9.2 ODE - CDRH - MDUFA IV Pre-Sub Performance Goals**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	1,726	588			
Written Feedback Provided by Day 70 Or 5 Days Prior to Meeting, Whichever is Sooner	1,575	539			

**Table 9.3 ODE - CDRH - Pre-Sub Time to MDUFA IV Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	1,726	588			
Average FDA Days to Written Feedback	59.63	59.57			
20th Percentile FDA Days to Written Feedback	49	49			
40th Percentile FDA Days to Written Feedback	59	60			
60th Percentile FDA Days to Written Feedback	65	65			
80th Percentile FDA Days to Written Feedback	70	70			
Maximum FDA Days to Written Feedback	172	131			

**Table 9.4 ODE - CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Scheduling**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meetings Not Scheduled By Day 30	31	16			
Average Days to Scheduling for Meetings Scheduled After Day 30	35.94	34.81			

**Table 9.5 ODE - CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Minutes**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Meeting Held	1,029	321			
Meeting Minutes Submitted Within 15 Days of Meeting	667	186			
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	24			
Meeting Minutes Past 15 Days of Meeting	325	87			
Meeting Minutes Not Submitted and >15 Days Since Meeting	37	24			
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	64.82%	62.63%			

## Section 9 Pre-Sub Office Level Metrics

**Table 9.1 OIR - CDRH - Pre-Sub Acceptance Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	885	517			
Closed Before RTA Action	8	4			
Number Accepted First RTA Cycle	869	482			
Number Without a RTA Review and > 15 Days Since Date Received	0	4			
Number Without a RTA Review and <= 15 Days Since Date Received	0	22			
Number Not Accepted	8	5			
Rate of Submissions Not Accepted for Review	0.91%	1.02%			

**Table 9.2 OIR - CDRH - MDUFA IV Pre-Sub Performance Goals**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	867	331			
Written Feedback Provided by Day 70 Or 5 Days Prior to Meeting, Whichever is Sooner	863	328			

**Table 9.3 OIR - CDRH - Pre-Sub Time to MDUFA IV Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	867	331			
Average FDA Days to Written Feedback	57.32	53.84			
20th Percentile FDA Days to Written Feedback	48	41			
40th Percentile FDA Days to Written Feedback	57	55			
60th Percentile FDA Days to Written Feedback	63	61			
80th Percentile FDA Days to Written Feedback	68	67			
Maximum FDA Days to Written Feedback	85	70			

**Table 9.4 OIR - CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Scheduling**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meetings Not Scheduled By Day 30	6	3			
Average Days to Scheduling for Meetings Scheduled After Day 30	33.83	38.00			

**Table 9.5 OIR - CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Minutes**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Meeting Held	473	174			
Meeting Minutes Submitted Within 15 Days of Meeting	304	99			
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	19			
Meeting Minutes Past 15 Days of Meeting	151	46			
Meeting Minutes Not Submitted and >15 Days Since Meeting	18	10			
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	64.27%	63.87%			

## Section 9 Pre-Sub Division Level Metrics

Table 9.1 DAGRID - ODE - CDRH - MDUFA IV Pre-Sub Acceptance Review Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	332	169			
Closed Before RTA Action	3	1			
Number Accepted First RTA Cycle	284	136			
Number Without a RTA Review and > 15 Days Since Date Received	12	5			
Number Without a RTA Review and <= 15 Days Since Date Received	0	14			
Number Not Accepted	33	13			
Rate of Submissions Not Accepted for Review	10.03%	8.44%			

Table 9.2 DAGRID - ODE - CDRH - MDUFA IV Pre-Sub Performance Goals

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	300	101			
Written Feedback Provided by Day 70 Or 5 Days Prior to Meeting, Whichever is Sooner	254	88			

Table 9.3 DAGRID - ODE - CDRH - Pre-Sub Time to MDUFA IV Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	300	101			
Average FDA Days to Written Feedback	64.31	61.33			
20th Percentile FDA Days to Written Feedback	57	55			
40th Percentile FDA Days to Written Feedback	64	63			
60th Percentile FDA Days to Written Feedback	68	68			
80th Percentile FDA Days to Written Feedback	70	70			
Maximum FDA Days to Written Feedback	168	78			

Table 9.4 DAGRID - ODE - CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Scheduling

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meetings Not Scheduled By Day 30	10	5			
Average Days to Scheduling for Meetings Scheduled After Day 30	41.30	33.40			

**Table 9.5 DAGRID - ODE - CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Minutes**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Meeting Held	171	61			
Meeting Minutes Submitted Within 15 Days of Meeting	114	33			
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	6			
Meeting Minutes Past 15 Days of Meeting	46	18			
Meeting Minutes Not Submitted and >15 Days Since Meeting	11	4			
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	66.67%	60.00%			



**Section 9 Pre-Sub Division Level Metrics**

**Table 9.1 DCD - ODE - CDRH - MDUFA IV Pre-Sub Acceptance Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	534	261			
Closed Before RTA Action	6	4			
Number Accepted First RTA Cycle	510	238			
Number Without a RTA Review and > 15 Days Since Date Received	12	6			
Number Without a RTA Review and <= 15 Days Since Date Received	0	11			
Number Not Accepted	6	2			
Rate of Submissions Not Accepted for Review	1.14%	0.81%			

**Table 9.2 DCD - ODE - CDRH - MDUFA IV Pre-Sub Performance Goals**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	516	176			
Written Feedback Provided by Day 70 Or 5 Days Prior to Meeting, Whichever is Sooner	484	168			

**Table 9.3 DCD - ODE - CDRH - Pre-Sub Time to MDUFA IV Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	516	176			
Average FDA Days to Written Feedback	53.11	54.10			
20th Percentile FDA Days to Written Feedback	39	43			
40th Percentile FDA Days to Written Feedback	50	51			
60th Percentile FDA Days to Written Feedback	59	60			
80th Percentile FDA Days to Written Feedback	67	66			
Maximum FDA Days to Written Feedback	91	115			

**Table 9.4 DCD - ODE - CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Scheduling**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meetings Not Scheduled By Day 30	8	5			
Average Days to Scheduling for Meetings Scheduled After Day 30	32.13	39.40			

**Table 9.5 DCD - ODE - CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Minutes**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Meeting Held	312	94			
Meeting Minutes Submitted Within 15 Days of Meeting	185	55			
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	3			
Meeting Minutes Past 15 Days of Meeting	117	28			
Meeting Minutes Not Submitted and >15 Days Since Meeting	10	8			
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	59.29%	60.44%			

## Section 9 Pre-Sub Division Level Metrics

Table 9.1 DNPMD - ODE - CDRH - MDUFA IV Pre-Sub Acceptance Review Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	249	131			
Closed Before RTA Action	3	1			
Number Accepted First RTA Cycle	232	114			
Number Without a RTA Review and > 15 Days Since Date Received	7	0			
Number Without a RTA Review and <= 15 Days Since Date Received	0	10			
Number Not Accepted	7	6			
Rate of Submissions Not Accepted for Review	2.85%	5.00%			

Table 9.2 DNPMD - ODE - CDRH - MDUFA IV Pre-Sub Performance Goals

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	235	78			
Written Feedback Provided by Day 70 Or 5 Days Prior to Meeting, Whichever is Sooner	202	62			

Table 9.3 DNPMD - ODE - CDRH - Pre-Sub Time to MDUFA IV Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	235	78			
Average FDA Days to Written Feedback	64.72	68.45			
20th Percentile FDA Days to Written Feedback	58	61			
40th Percentile FDA Days to Written Feedback	65	66			
60th Percentile FDA Days to Written Feedback	69	70			
80th Percentile FDA Days to Written Feedback	70	70			
Maximum FDA Days to Written Feedback	172	131			

Table 9.4 DNPMD - ODE - CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Scheduling

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meetings Not Scheduled By Day 30	5	2			
Average Days to Scheduling for Meetings Scheduled After Day 30	34.20	32.50			

**Table 9.5 DNPMD - ODE - CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Minutes**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Meeting Held	154	41			
Meeting Minutes Submitted Within 15 Days of Meeting	99	24			
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	3			
Meeting Minutes Past 15 Days of Meeting	50	10			
Meeting Minutes Not Submitted and >15 Days Since Meeting	5	4			
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	64.29%	63.16%			

## Section 9 Pre-Sub Division Level Metrics

Table 9.1 DOD - ODE - CDRH - MDUFA IV Pre-Sub Acceptance Review Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	133	73			
Closed Before RTA Action	1	2			
Number Accepted First RTA Cycle	127	58			
Number Without a RTA Review and > 15 Days Since Date Received	5	3			
Number Without a RTA Review and <= 15 Days Since Date Received	0	8			
Number Not Accepted	0	2			
Rate of Submissions Not Accepted for Review	0%	3.17%			

Table 9.2 DOD - ODE - CDRH - MDUFA IV Pre-Sub Performance Goals

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	129	38			
Written Feedback Provided by Day 70 Or 5 Days Prior to Meeting, Whichever is Sooner	115	35			

Table 9.3 DOD - ODE - CDRH - Pre-Sub Time to MDUFA IV Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	129	38			
Average FDA Days to Written Feedback	61.91	59.26			
20th Percentile FDA Days to Written Feedback	52	54			
40th Percentile FDA Days to Written Feedback	62	58			
60th Percentile FDA Days to Written Feedback	67	63			
80th Percentile FDA Days to Written Feedback	70	67			
Maximum FDA Days to Written Feedback	106	70			

Table 9.4 DOD - ODE - CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Scheduling

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meetings Not Scheduled By Day 30	3	1			
Average Days to Scheduling for Meetings Scheduled After Day 30	33.00	33.00			

**Table 9.5 DOD - ODE - CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Minutes**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Meeting Held	77	17			
Meeting Minutes Submitted Within 15 Days of Meeting	55	11			
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0			
Meeting Minutes Past 15 Days of Meeting	18	3			
Meeting Minutes Not Submitted and >15 Days Since Meeting	4	3			
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	71.43%	64.71%			

## Section 9 Pre-Sub Division Level Metrics

**Table 9.1 DOED - ODE - CDRH - MDUFA IV Pre-Sub Acceptance Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	128	82			
Closed Before RTA Action	0	2			
Number Accepted First RTA Cycle	118	71			
Number Without a RTA Review and > 15 Days Since Date Received	5	1			
Number Without a RTA Review and <= 15 Days Since Date Received	0	6			
Number Not Accepted	5	2			
Rate of Submissions Not Accepted for Review	3.91%	2.70%			

**Table 9.2 DOED - ODE - CDRH - MDUFA IV Pre-Sub Performance Goals**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	120	49			
Written Feedback Provided by Day 70 Or 5 Days Prior to Meeting, Whichever is Sooner	117	49			

**Table 9.3 DOED - ODE - CDRH - Pre-Sub Time to MDUFA IV Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	120	49			
Average FDA Days to Written Feedback	62.38	62.80			
20th Percentile FDA Days to Written Feedback	57	57			
40th Percentile FDA Days to Written Feedback	63	64			
60th Percentile FDA Days to Written Feedback	66	67			
80th Percentile FDA Days to Written Feedback	70	70			
Maximum FDA Days to Written Feedback	73	70			

**Table 9.4 DOED - ODE - CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Scheduling**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meetings Not Scheduled By Day 30	2	0			
Average Days to Scheduling for Meetings Scheduled After Day 30	37.00	0			

**Table 9.5 DOED - ODE - CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Minutes**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Meeting Held	78	33			
Meeting Minutes Submitted Within 15 Days of Meeting	57	22			
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	4			
Meeting Minutes Past 15 Days of Meeting	20	5			
Meeting Minutes Not Submitted and >15 Days Since Meeting	1	2			
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	73.08%	75.86%			



## Section 9 Pre-Sub Division Level Metrics

Table 9.1 DRGUD - ODE - CDRH - MDUFA IV Pre-Sub Acceptance Review Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	231	133			
Closed Before RTA Action	2	3			
Number Accepted First RTA Cycle	225	122			
Number Without a RTA Review and > 15 Days Since Date Received	2	0			
Number Without a RTA Review and <= 15 Days Since Date Received	0	7			
Number Not Accepted	2	1			
Rate of Submissions Not Accepted for Review	0.87%	0.81%			

Table 9.2 DRGUD - ODE - CDRH - MDUFA IV Pre-Sub Performance Goals

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	224	76			
Written Feedback Provided by Day 70 Or 5 Days Prior to Meeting, Whichever is Sooner	219	73			

Table 9.3 DRGUD - ODE - CDRH - Pre-Sub Time to MDUFA IV Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	224	76			
Average FDA Days to Written Feedback	59.75	57.68			
20th Percentile FDA Days to Written Feedback	51	49			
40th Percentile FDA Days to Written Feedback	60	59			
60th Percentile FDA Days to Written Feedback	65	64			
80th Percentile FDA Days to Written Feedback	69	68			
Maximum FDA Days to Written Feedback	156	91			

Table 9.4 DRGUD - ODE - CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Scheduling

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meetings Not Scheduled By Day 30	1	3			
Average Days to Scheduling for Meetings Scheduled After Day 30	33.00	31.67			

**Table 9.5 DRGUD - ODE - CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Minutes**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Meeting Held	128	36			
Meeting Minutes Submitted Within 15 Days of Meeting	76	17			
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	5			
Meeting Minutes Past 15 Days of Meeting	51	14			
Meeting Minutes Not Submitted and >15 Days Since Meeting	1	0			
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	59.38%	54.84%			

## Section 9 Pre-Sub Division Level Metrics

Table 9.1 DSD - ODE - CDRH - MDUFA IV Pre-Sub Acceptance Review Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	215	105			
Closed Before RTA Action	4	3			
Number Accepted First RTA Cycle	200	91			
Number Without a RTA Review and > 15 Days Since Date Received	6	5			
Number Without a RTA Review and <= 15 Days Since Date Received	0	6			
Number Not Accepted	5	0			
Rate of Submissions Not Accepted for Review	2.37%	0%			

Table 9.2 DSD - ODE - CDRH - MDUFA IV Pre-Sub Performance Goals

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	202	70			
Written Feedback Provided by Day 70 Or 5 Days Prior to Meeting, Whichever is Sooner	184	64			

Table 9.3 DSD - ODE - CDRH - Pre-Sub Time to MDUFA IV Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	202	70			
Average FDA Days to Written Feedback	60.23	60.86			
20th Percentile FDA Days to Written Feedback	51	51			
40th Percentile FDA Days to Written Feedback	58	62			
60th Percentile FDA Days to Written Feedback	64	64			
80th Percentile FDA Days to Written Feedback	69	70			
Maximum FDA Days to Written Feedback	121	92			

Table 9.4 DSD - ODE - CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Scheduling

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meetings Not Scheduled By Day 30	2	0			
Average Days to Scheduling for Meetings Scheduled After Day 30	33.50	0			

**Table 9.5 DSD - ODE - CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Minutes**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Meeting Held	109	39			
Meeting Minutes Submitted Within 15 Days of Meeting	81	24			
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	3			
Meeting Minutes Past 15 Days of Meeting	23	9			
Meeting Minutes Not Submitted and >15 Days Since Meeting	5	3			
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	74.31%	66.67%			

## Section 9 Pre-Sub Division Level Metrics

Table 9.1 DCTD - OIR - CDRH - MDUFA IV Pre-Sub Acceptance Review Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	220	132			
Closed Before RTA Action	3	1			
Number Accepted First RTA Cycle	216	126			
Number Without a RTA Review and > 15 Days Since Date Received	0	0			
Number Without a RTA Review and <= 15 Days Since Date Received	0	5			
Number Not Accepted	1	0			
Rate of Submissions Not Accepted for Review	0.46%	0%			

Table 9.2 DCTD - OIR - CDRH - MDUFA IV Pre-Sub Performance Goals

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	216	86			
Written Feedback Provided by Day 70 Or 5 Days Prior to Meeting, Whichever is Sooner	215	84			

Table 9.3 DCTD - OIR - CDRH - Pre-Sub Time to MDUFA IV Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	216	86			
Average FDA Days to Written Feedback	56.98	54.71			
20th Percentile FDA Days to Written Feedback	46	41			
40th Percentile FDA Days to Written Feedback	58	56			
60th Percentile FDA Days to Written Feedback	63	63			
80th Percentile FDA Days to Written Feedback	68	67			
Maximum FDA Days to Written Feedback	71	70			

Table 9.4 DCTD - OIR - CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Scheduling

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meetings Not Scheduled By Day 30	2	1			
Average Days to Scheduling for Meetings Scheduled After Day 30	36.00	47.00			

**Table 9.5 DCTD - OIR - CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Minutes**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Meeting Held	126	54			
Meeting Minutes Submitted Within 15 Days of Meeting	87	29			
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	6			
Meeting Minutes Past 15 Days of Meeting	34	14			
Meeting Minutes Not Submitted and >15 Days Since Meeting	5	5			
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	69.05%	60.42%			

## Section 9 Pre-Sub Division Level Metrics

Table 9.1 DIHD - OIR - CDRH - MDUFA IV Pre-Sub Acceptance Review Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	117	69			
Closed Before RTA Action	4	1			
Number Accepted First RTA Cycle	113	62			
Number Without a RTA Review and > 15 Days Since Date Received	0	1			
Number Without a RTA Review and <= 15 Days Since Date Received	0	5			
Number Not Accepted	0	0			
Rate of Submissions Not Accepted for Review	0%	0%			

Table 9.2 DIHD - OIR - CDRH - MDUFA IV Pre-Sub Performance Goals

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	112	36			
Written Feedback Provided by Day 70 Or 5 Days Prior to Meeting, Whichever is Sooner	111	36			

Table 9.3 DIHD - OIR - CDRH - Pre-Sub Time to MDUFA IV Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	112	36			
Average FDA Days to Written Feedback	62.68	58.06			
20th Percentile FDA Days to Written Feedback	57	44			
40th Percentile FDA Days to Written Feedback	63	64			
60th Percentile FDA Days to Written Feedback	67	66			
80th Percentile FDA Days to Written Feedback	70	69			
Maximum FDA Days to Written Feedback	71	70			

Table 9.4 DIHD - OIR - CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Scheduling

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meetings Not Scheduled By Day 30	3	1			
Average Days to Scheduling for Meetings Scheduled After Day 30	33.33	31.00			

**Table 9.5 DIHD - OIR - CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Minutes**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Meeting Held	70	20			
Meeting Minutes Submitted Within 15 Days of Meeting	49	10			
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	3			
Meeting Minutes Past 15 Days of Meeting	17	6			
Meeting Minutes Not Submitted and >15 Days Since Meeting	4	1			
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	70.00%	58.82%			



## Section 9 Pre-Sub Division Level Metrics

Table 9.1 DMD - OIR - CDRH - MDUFA IV Pre-Sub Acceptance Review Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	224	118			
Closed Before RTA Action	0	0			
Number Accepted First RTA Cycle	223	114			
Number Without a RTA Review and > 15 Days Since Date Received	0	0			
Number Without a RTA Review and <= 15 Days Since Date Received	0	3			
Number Not Accepted	1	1			
Rate of Submissions Not Accepted for Review	0.45%	0.87%			

Table 9.2 DMD - OIR - CDRH - MDUFA IV Pre-Sub Performance Goals

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	222	77			
Written Feedback Provided by Day 70 Or 5 Days Prior to Meeting, Whichever is Sooner	221	77			

Table 9.3 DMD - OIR - CDRH - Pre-Sub Time to MDUFA IV Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	222	77			
Average FDA Days to Written Feedback	57.66	52.22			
20th Percentile FDA Days to Written Feedback	48	38			
40th Percentile FDA Days to Written Feedback	58	52			
60th Percentile FDA Days to Written Feedback	65	58			
80th Percentile FDA Days to Written Feedback	69	66			
Maximum FDA Days to Written Feedback	85	70			

Table 9.4 DMD - OIR - CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Scheduling

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meetings Not Scheduled By Day 30	0	0			
Average Days to Scheduling for Meetings Scheduled After Day 30	0	0			

**Table 9.5 DMD - OIR - CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Minutes**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Meeting Held	70	27			
Meeting Minutes Submitted Within 15 Days of Meeting	33	14			
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	3			
Meeting Minutes Past 15 Days of Meeting	30	8			
Meeting Minutes Not Submitted and >15 Days Since Meeting	7	2			
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	47.14%	58.33%			

## Section 9 Pre-Sub Division Level Metrics

**Table 9.1 DMGP - OIR - CDRH - MDUFA IV Pre-Sub Acceptance Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	192	110			
Closed Before RTA Action	0	0			
Number Accepted First RTA Cycle	191	102			
Number Without a RTA Review and > 15 Days Since Date Received	0	2			
Number Without a RTA Review and <= 15 Days Since Date Received	0	6			
Number Not Accepted	1	0			
Rate of Submissions Not Accepted for Review	0.52%	0%			

**Table 9.2 DMGP - OIR - CDRH - MDUFA IV Pre-Sub Performance Goals**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	190	74			
Written Feedback Provided by Day 70 Or 5 Days Prior to Meeting, Whichever is Sooner	190	74			

**Table 9.3 DMGP - OIR - CDRH - Pre-Sub Time to MDUFA IV Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	190	74			
Average FDA Days to Written Feedback	58.03	54.49			
20th Percentile FDA Days to Written Feedback	51	43			
40th Percentile FDA Days to Written Feedback	59	56			
60th Percentile FDA Days to Written Feedback	63	61			
80th Percentile FDA Days to Written Feedback	67	66			
Maximum FDA Days to Written Feedback	70	70			

**Table 9.4 DMGP - OIR - CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Scheduling**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meetings Not Scheduled By Day 30	0	0			
Average Days to Scheduling for Meetings Scheduled After Day 30	0	0			

**Table 9.5 DMGP - OIR - CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Minutes**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Meeting Held	121	41			
Meeting Minutes Submitted Within 15 Days of Meeting	70	25			
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	4			
Meeting Minutes Past 15 Days of Meeting	50	12			
Meeting Minutes Not Submitted and >15 Days Since Meeting	1	0			
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	57.85%	67.57%			

## Section 9 Pre-Sub Division Level Metrics

Table 9.1 DRH - OIR - CDRH - MDUFA IV Pre-Sub Acceptance Review Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	132	88			
Closed Before RTA Action	1	2			
Number Accepted First RTA Cycle	126	78			
Number Without a RTA Review and > 15 Days Since Date Received	0	1			
Number Without a RTA Review and <= 15 Days Since Date Received	0	3			
Number Not Accepted	5	4			
Rate of Submissions Not Accepted for Review	3.82%	4.82%			

Table 9.2 DRH - OIR - CDRH - MDUFA IV Pre-Sub Performance Goals

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	127	58			
Written Feedback Provided by Day 70 Or 5 Days Prior to Meeting, Whichever is Sooner	126	57			

Table 9.3 DRH - OIR - CDRH - Pre-Sub Time to MDUFA IV Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	127	58			
Average FDA Days to Written Feedback	51.53	51.24			
20th Percentile FDA Days to Written Feedback	43	38			
40th Percentile FDA Days to Written Feedback	49	52			
60th Percentile FDA Days to Written Feedback	56	56			
80th Percentile FDA Days to Written Feedback	61	63			
Maximum FDA Days to Written Feedback	70	70			

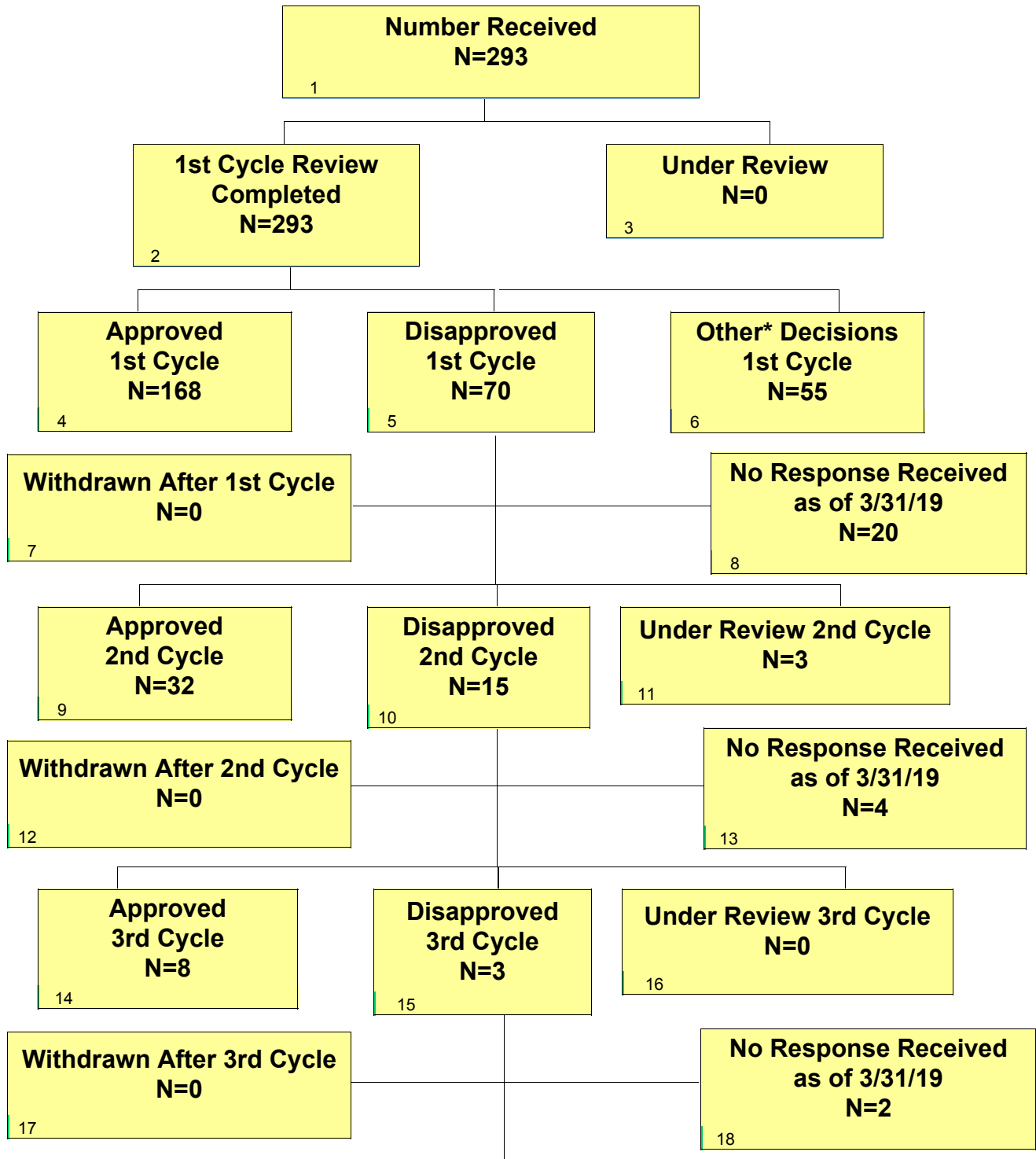
Table 9.4 DRH - OIR - CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Scheduling

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meetings Not Scheduled By Day 30	1	1			
Average Days to Scheduling for Meetings Scheduled After Day 30	31.00	36.00			

**Table 9.5 DRH - OIR - CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Minutes**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Meeting Held	86	32			
Meeting Minutes Submitted Within 15 Days of Meeting	65	21			
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	3			
Meeting Minutes Past 15 Days of Meeting	20	6			
Meeting Minutes Not Submitted and >15 Days Since Meeting	1	2			
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	75.58%	72.41%			

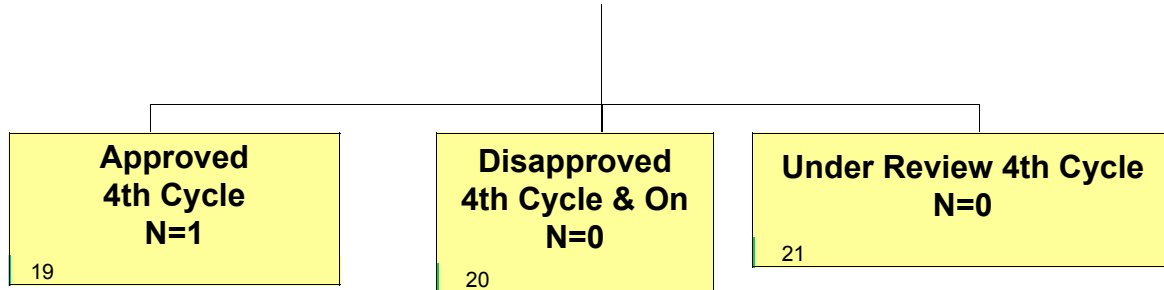
# CDRH IDEs - FY 2018 as of 3/31/19



\* Other decisions include withdrawn (N=10), withdrawn and converted (N=31), RTA (N=0), nonsignificant risk device (N=11), exempt (N=1), product jurisdiction pending (N=0), or product jurisdiction transferred (N=2), Basic Physiological Research (N=0).

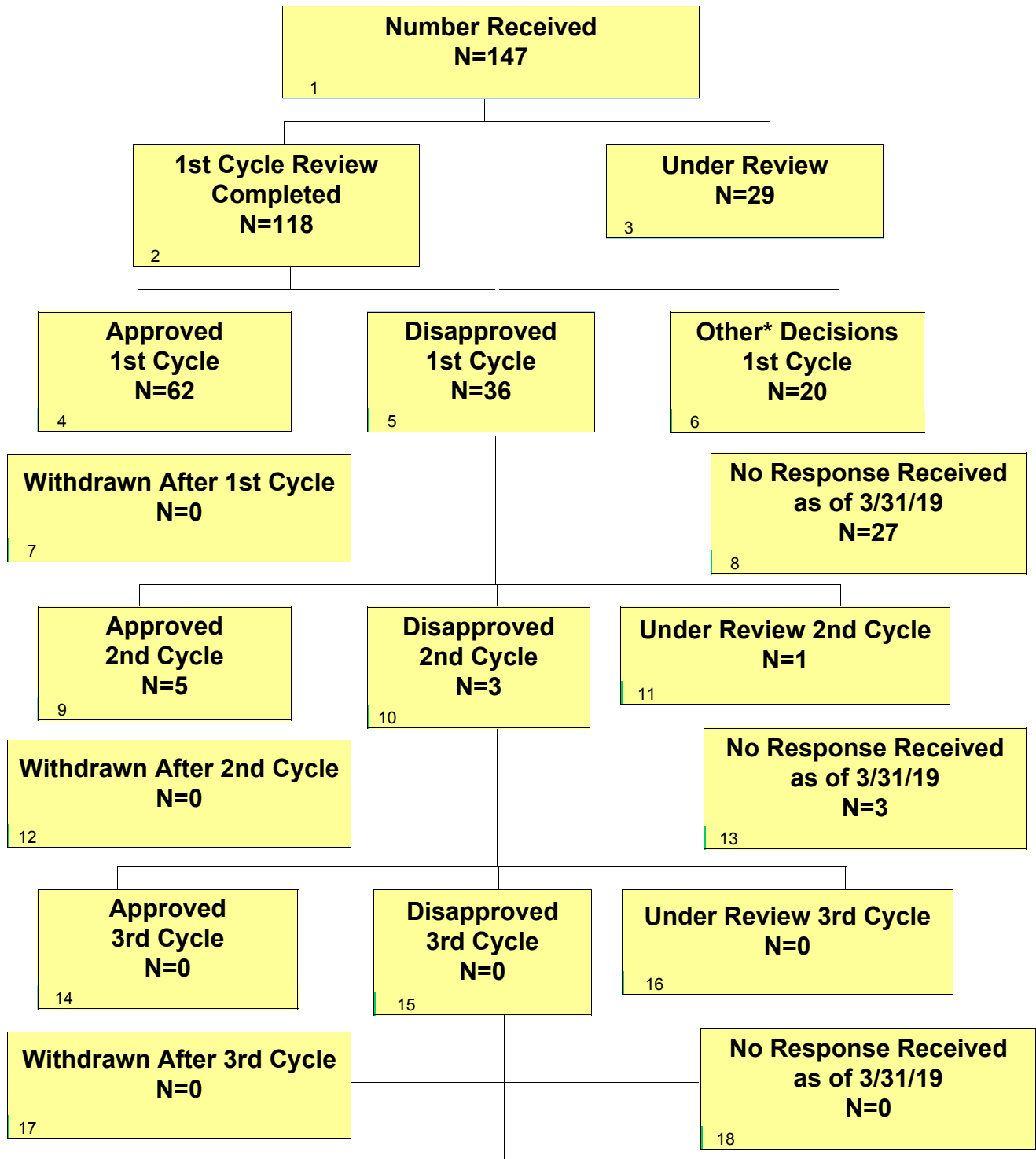
# CDRH IDEs - FY 2018 as of 3/31/19

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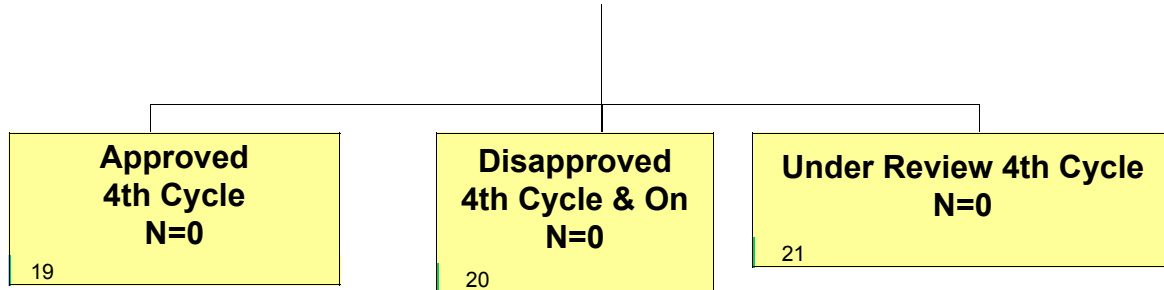
# CDRH IDEs - FY 2019 as of 3/31/19



\* Other decisions include withdrawn (N=2), withdrawn and converted (N=10), RTA (N=0), nonsignificant risk device (N=5), exempt (N=0), product jurisdiction pending (N=2), or product jurisdiction transferred (N=1), Basic Physiological Research (N=0).

# CDRH IDEs - FY 2019 as of 3/31/19

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## Section 10 IDE- Center Level Metric

Table 10.1 CDRH - IDE MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of IDEs Received	293	147			
Average Number of Cycles to IDE Approval or Conditional Approval	1.24	1.07			
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.24	0.07			

## Section 10 IDE - Office Level Metric

Table 10.1 ODE - CDRH - IDE MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of IDEs Received	241	121			
Average Number of Cycles to IDE Approval or Conditional Approval	1.31	1.09			
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.31	0.09			

## Section 10 IDE - Office Level Metric

Table 10.1 OIR - CDRH - IDE MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of IDEs Received	52	26			
Average Number of Cycles to IDE Approval or Conditional Approval	1.00	1.00			
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.00	0.00			

## Section 10 IDE - Division Level Metric

Table 10.1 DAGRID - ODE - CDRH - IDE MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of IDEs received	14	10			
Average Number of Cycles to IDE Approval or Conditional Approval	1.33	1.00			
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.33	0.00			

## Section 10 IDE - Division Level Metric

Table 10.1 DCD - ODE - CDRH - IDE MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of IDEs received	57	31			
Average Number of Cycles to IDE Approval or Conditional Approval	1.41	1.06			
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.41	0.06			

## Section 10 IDE - Division Level Metric

Table 10.1 DNPMD - ODE - CDRH - IDE MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of IDEs received	61	32			
Average Number of Cycles to IDE Approval or Conditional Approval	1.12	1.14			
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.12	0.14			

## Section 10 IDE - Division Level Metric

Table 10.1 DOD - ODE - CDRH - IDE MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of IDEs received	17	7			
Average Number of Cycles to IDE Approval or Conditional Approval	1.09	1.00			
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.09	0.00			

## Section 10 IDE - Division Level Metric

Table 10.1 DOED - ODE - CDRH - IDE MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of IDEs received	32	14			
Average Number of Cycles to IDE Approval or Conditional Approval	1.31	1.00			
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.31	0.00			

## Section 10 IDE - Division Level Metric

Table 10.1 DRGUD - ODE - CDRH - IDE MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of IDEs received	31	17			
Average Number of Cycles to IDE Approval or Conditional Approval	1.59	1.20			
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.59	0.20			

## Section 10 IDE - Division Level Metric

Table 10.1 DSD - ODE - CDRH - IDE MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of IDEs received	29	10			
Average Number of Cycles to IDE Approval or Conditional Approval	1.25	1.33			
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.25	0.33			

## Section 10 IDE - Division Level Metric

Table 10.1 DCTD - OIR - CDRH - IDE MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of IDEs received	24	15			
Average Number of Cycles to IDE Approval or Conditional Approval	1.00	1.00			
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.00	0.00			

## Section 10 IDE - Division Level Metric

Table 10.1 DIHD - OIR - CDRH - IDE MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of IDEs received	1	1			
Average Number of Cycles to IDE Approval or Conditional Approval	N/A	1.00			
Average Number of Amendments Prior to IDE Approval or Conditional Approval	N/A	0.00			

## Section 10 IDE - Division Level Metric

Table 10.1 DMD - OIR - CDRH - IDE MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of IDEs received	2	1			
Average Number of Cycles to IDE Approval or Conditional Approval	1.00	N/A			
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.00	N/A			

## Section 10 IDE - Division Level Metric

Table 10.1 DMGP - OIR - CDRH - IDE MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of IDEs received	17	4			
Average Number of Cycles to IDE Approval or Conditional Approval	1.00	1.00			
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.00	0.00			

## Section 10 IDE - Division Level Metric

Table 10.1 DRH - OIR - CDRH - IDE MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of IDEs received	8	5			
Average Number of Cycles to IDE Approval or Conditional Approval	1.00	N/A			
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.00	N/A			

## **Section 11      CLIA Waiver Annual Metrics**

CLIA Waiver Annual Metrics and Goals will be reported in the Annual Report.

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## **Section 12 Dual (510(k) and CLIA Waiver) Annual Metrics**

Dual (510(k) and CLIA Waiver) Annual Metrics and Goals will be reported in the Annual Report.

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## Appendix A Variable Definitions

### Section 1 PMA Originals and Panel Track Supplements

**Table 1.1 and Tables 1.1.x PMA Original and Panel Track Supplements – Acceptance Review Decision - Definitions**

#	Measure	Description
1	Number Received	Number of PMA Originals and Panel Track Supplements received in this fiscal year.
2	Closed before RTA action	Number Received (line 1) that were closed with a final decision before RTA action.
3	Number with accepted RTA review	Number Received (line 1) that got "RTA Accepted" (RTAA) or RTAX decision in the first RTA review cycle entered by reviewer.
4	Number without RTA Review and > 15 Days since Date Received	Number Received (line 1) that got "Did not perform RTA" (RTAN) decision in the first RTA review cycle automatically recorded by CTS at the end of day 15 of RTA review. These RTA reviews deemed approved.
5	Number without RTA Review and <= 15 Days since Date Received	Number Received (line 1) that are still in the first RTA review cycle.
6	Number Not Accepted for Filing Review	Number of submissions received in this fiscal year (line 1) that got a "Refuse to accept" (RTA1) decision in the first RTA review cycle.
7	Rate of submissions not accepted for filing review	Number Not Accepted for Filing Review (line 6) divided by the total of Number Accepted (line 3), Number without RTA Review and > 15 Days since Date Received (line 4), and Number Not Accepted for Filing Review (line 6).

**Table 1.2 and Tables 1.2.x****PMA Original and Panel Track Supplements – Filing Review Decision - Definitions**

#	Measure	Description
1	Number Received	Number of PMA Originals and Panel Track Supplements received in this fiscal year.
2	Number Accepted <sup>#</sup>	Number Received (line 1) that got "RTA Accepted" (RTAA) or RTAN decision in the first RTA review cycle entered by reviewer.
3	Number with completed RTF	Number of submissions with the first RTF review completed in this fiscal year.
4	Number Not Filed	Number of submissions with completed RTF (line 3) that got the NOFI decision in the first RTF review.
5	Rate of submissions Not Filed	Number Not Filed (line 4) divided by Number with completed RTF (line 3).

**Table 1.3 and Tables 1.3.x****PMA Originals & Panel Track Supplements Substantive Interaction Performance Goals - Definitions**

#	Measure	Description
1	Eligible for SI	Number of PMA Original submissions and Panel Track supplements that were filed in this fiscal year.
2	SI Goal Met	Number of submissions with SI action within goal.
3	SI Goal Not Met	Number of submissions with SI action taken past goal.
4	SI Pending Within Goal	Number of submissions that are under review with no SI within goal.
5	SI Pending Past Goal	Number of submissions that are under review with no SI past goal.
6	Closed without SI	Number of submissions that are closed with a MDUFA or final decision that does not qualify as SI and that did not have an SI prior to that decision (i.e., converted and withdrawn).
7	Current SI Performance Percent Goal Met	Number of submissions with SI within goal (line 2) divided by the total number of submissions that either had an SI (line 2 and line 3) or did not have an SI but failed the SI goal (line 5).

**Table 1.4 and Tables 1.4.x****PMA Originals and Panel Track Supplements Substantive Interaction Metrics – Time to Substantive Interaction - Definitions**

#	Measure	Description
1	Number of Substantive Interactions	Number of PMA Originals and Panel Track Supplements filed in this fiscal year that had an SI.
2	Average number of FDA days to Substantive Interaction	Average number of FDA days across all PMA Originals and Panel Track Supplements with SI (line 1).
3	20 <sup>th</sup> Percentile FDA days to Substantive Interaction	20 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
4	40 <sup>th</sup> Percentile FDA days to Substantive Interaction	40 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
5	60 <sup>th</sup> Percentile FDA days to Substantive Interaction	60 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
6	80 <sup>th</sup> Percentile FDA days to Substantive Interaction	80 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
7	Maximum FDA days to Substantive Interaction	Maximum FDA days (100 <sup>th</sup> percentile) to Substantive Interaction for submissions with SI (line 1).

**Tables 1.5 and Tables 1.5.x PMA Originals & Panel-Track Supplements (without Panel Review)  
MDUFA Decision Performance Goals - Definitions**

#	Measure	Description
1	Number of PMAs filed	Number of PMA Original submissions and Panel Track supplements that were filed in this fiscal year, and did not have Panel review requested.
2	Non-MDUFA IV Decisions	Submissions filed (line 1) and closed with a non-MDUFA IV decision (such as ABND, CONV, OTHR, RECL, XPMA).
3	MDUFA IV Decisions	Submissions filed (line 1) and closed with a MDUFA IV decision.
4	MDUFA IV Decisions Goal Met	Submissions with MDUFA IV decisions (line 3) made before or on the MDUFA goal due date.
5	PMAs pending MDUFA IV Decision	Number of submissions filed in this fiscal year (line 1) which do not have a MDUFA IV decision or final decision.
6	PMAs pending MDUFA IV Decision Past Goal	Number of submissions pending MDUFA IV Decision (line 5) past goal. These submissions already failed the MDUFA IV review goal.
7	Current Performance Percent Goal Met	Number of submissions with MDUFA IV Decisions made on time (line 4) divided by the total number of submissions with MDUFA IV Decisions (line 3) and pending submissions that already failed the MDUFA goal (line 6).

**Table 1.6 and Tables 1.6.x****PMA Originals & Panel Track Supplements (with Panel Review)  
MDUFA Decision Performance Goals - Definitions**

#	Measure	Description
1	Number of PMAs filed	Number of PMA Original submissions and Panel Track supplements that were filed in this fiscal year, and had a Panel review requested.
2	Non-MDUFA IV Decisions	Submissions filed (line 1) and closed with a non-MDUFA IV decision (such as ABND, CONV, OTHR, RECL, XPMA).
3	MDUFA IV Decisions	Submissions filed (line 1) and closed with a MDUFA IV decision.
4	MDUFA IV Decisions Goal Met	Submissions with MDUFA IV decisions (line 3) made before or on the MDUFA goal due date.
5	PMAs pending MDUFA IV Decision	Number of submissions filed in this fiscal year (line 1) which do not have a MDUFA IV decision or final decision.
6	PMAs pending MDUFA IV Decision Past Goal	Number of submissions pending MDUFA IV Decision (line 5) past goal. These submissions already failed the MDUFA IV review goal.
7	Current Performance Percent Goal Met	Number of submissions with MDUFA IV Decisions made on time (line 4) divided by the total number of submissions with MDUFA IV Decisions (line 3) and pending submissions that already failed the MDUFA goal (line 6).

**Table 1.7 and Tables 1.7.x****PMA Original and Panel Track Supplements (without Panel Review)  
Performance Metrics – Time to MDUFA Decision - Definitions**

#	Measure	Description
1	Number with MDUFA IV Decision	Number of PMA Original submissions and Panel Track supplements that were filed in this fiscal year, did not have Panel review requested, and had a MDUFA decision made before or on the report cutoff date.
	Days to MDUFA Decision	Table shall show Average Days to MDUFA IV decision as well as quintiles (20 <sup>th</sup> , 40 <sup>th</sup> , 60 <sup>th</sup> , 80 <sup>th</sup> percentiles) and the Maximum Days (100 <sup>th</sup> percentile) for FDA days, Industry days, and Total days.



**Table 1.8 and Tables 1.8.x PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Time to MDUFA Decision - Definitions**

#	Measure	Description
1	Number with MDUFA IV Decision	Number of PMA Original submissions and Panel Track supplements that were filed in this fiscal year, had Panel review requested, and had a MDUFA decision made before or on the report cutoff date.
	Days to MDUFA Decision	Table shall show Average Days to MDUFA IV decision as well as quintiles (20 <sup>th</sup> , 40 <sup>th</sup> , 60 <sup>th</sup> , 80 <sup>th</sup> percentiles) and the Maximum Days (100 <sup>th</sup> percentile) for FDA days, Industry days, and Total days.

**Table 1.9 and Tables 1.9.x PMA Originals and Panel Track Supplements (without Panel Review) Performance Metrics – Rate of Withdrawal and Not Approvable - Definitions**

#	Measure	Description
1	Number Filed	Number of PMA Originals and Panel Track Supplements that were filed in this fiscal year, and did not have Panel Review requested.
2	Number with MDUFA IV decision	Number submissions filed (line 1) that also had a MDUFA decision.
3	Number of Withdrawals	Number of submissions filed (line 1) with MDUFA decision of WTDR (Withdrawn).
4	Number of Not Approvable	Number of submissions filed (line 1) with MDUFA decision of NOAP (Not Approvable).
5	Number of Deleted	Number of submissions filed (line 1) with MDUFA decision of DELE (Deleted).
6	Rate of Withdrawals	Number of Withdrawals (line 3) divided by Number with MDUFA decision (line 2).
7	Rate of Not Approvable	Number of Not Approvable (line 4) divided by Number with MDUFA decision (line 2).

**Table 1.10 and Tables 1.10.x PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Rate of Withdrawal and Not Approvable - Definitions**

#	Measure	Description
1	Number Filed	Number of PMA Originals and Panel Track Supplements that were filed in this fiscal year, and had Panel Review requested.
2	Number with MDUFA decision	Number submissions filed (line 1) that also had a MDUFA decision.
3	Number of Withdrawals	Number of submissions filed (line 1) with MDUFA decision of WTDR (Withdrawn).
4	Number of Not Approvable	Number of submissions filed (line 1) with MDUFA decision of NOAP (Not Approvable).
5	Number of Deleted	Number of submissions filed (line 1) with MDUFA decision of DELE (Deleted).
6	Rate of Withdrawals	Number of Withdrawals (line 3) divided by Number with MDUFA decision (line 2).
7	Rate of Not Approvable	Number of Not Approvable (line 4) divided by Number with MDUFA decision (line2).

**Table 1.11 and Tables 1.11.x PMA Original and Panel Track Supplements (without Panel Review) Performance Metrics – Submissions Missing Performance Goals - Definitions**

#	Measure	Description
1	Number of submissions that missed the goal	Number of PMA Originals and Panel Track Supplements, filed in this fiscal year, without Panel Review, with number FDA days to MDUFA IV decision exceeding number of goal days.
2	Mean FDA days for submissions that missed goal	Mean FDA days for submissions that missed the goal (line 1).
3	Mean industry days for submissions that missed goal	Mean industry days for submissions that missed the goal (line 1).

**Table 1.12 and Tables 1.12.x PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Submissions Missing Performance Goals - Definitions**

#	Measure	Description
1	Number of submissions that missed the goal	Number of PMA Originals and Panel Track Supplements, filed in this fiscal year, with Panel Review, with number FDA days to MDUFA IV decision exceeding number of goal days.
2	Mean FDA days for submissions that missed goal	Mean FDA days for submissions that missed the goal (line 1).
3	Mean industry days for submissions that missed goal	Mean industry days for submissions that missed the goal (line 1).

**Tables 1.13 and Tables 1.13.x LDT PMA Originals & Panel-Track Supplements Metric\* MDUFA Decision Performance Goals - Definitions**

#	Measure	Description
1	Number of PMAs filed	Number of PMA Original submissions and Panel Track supplements that were filed in this fiscal year.
2	Non-MDUFA IV Decisions	Submissions filed (line 1) and closed with a non-MDUFA IV decision (such as ABND, CONV, OTHR, RECL, XPMA).
3	MDUFA IV Decisions	Submissions filed (line 1) and closed with a MDUFA IV decision.
4	MDUFA IV Decisions Goal Met	Submissions with MDUFA IV decisions (line 3) made before or on the MDUFA goal due date.
5	PMAs pending MDUFA IV Decision	Number of submissions filed in this fiscal year (line 1) which do not have a MDUFA IV decision or final decision.
6	PMAs pending MDUFA IV Decision Past Goal	Number of submissions pending MDUFA IV Decision (line 5) past goal. These submissions already failed the MDUFA IV review goal.
7	Current Performance Percent Goal Met	Number of submissions with MDUFA IV Decisions made on time (line 4) divided by the total number of submissions with MDUFA IV Decisions (line 3) and pending submissions that already failed the MDUFA goal (line 6).

\*Includes submissions that went to panel

**Tables 1.14 and Tables 1.14.x Conventional IVD (Non-LDT) PMA Originals & Panel-Track Supplements Metric\* MDUFA Decision Performance Goals - Definitions**

#	Measure	Description
1	Number of PMAs filed	Number of PMA Original submissions and Panel Track supplements that were filed in this fiscal year.
2	Non-MDUFA IV Decisions	Submissions filed (line 1) and closed with a non-MDUFA IV decision (such as ABND, CONV, OTHR, RECL, XPMA).
3	MDUFA IV Decisions	Submissions filed (line 1) and closed with a MDUFA IV decision.
4	MDUFA IV Decisions Goal Met	Submissions with MDUFA IV decisions (line 3) made before or on the MDUFA goal due date.
5	PMAs pending MDUFA IV Decision	Number of submissions filed in this fiscal year (line 1) which do not have a MDUFA IV decision or final decision.
6	PMAs pending MDUFA IV Decision Past Goal	Number of submissions pending MDUFA IV Decision (line 5) past goal. These submissions already failed the MDUFA IV review goal.
7	Current Performance Percent Goal Met	Number of submissions with MDUFA IV Decisions made on time (line 4) divided by the total number of submissions with MDUFA IV Decisions (line 3) and pending submissions that already failed the MDUFA goal (line 6).

\*Includes submissions that went to panel

## Section 2 PMA 180 Day Supplements

**Table 2.1 and Tables 2.1.x PMA 180 Day Supplements Substantive Interaction Goals – Definitions**

#	Measure	Description
1	Eligible for SI	Number of 180 day PMA supplements received in this fiscal year.
2	SI Goal Met	Number of submissions with an SI action taken within goal.
3	SI Goal Not Met	Number of submissions with an SI action taken past goal.
4	SI Pending Within Goal	Submissions that are under review within goal.
5	SI Pending Past Goal	Submissions that are under review past goal.
6	Closed without SI	Number of submissions that are closed with a MDUFA (other than APPR) or NON-MDUFA decision but without an SI
7	Current SI Performance Percent Goal Met	Number of submissions with SI within goal (line 2) divided by the total number of submissions that either had an SI (line 2 and line 3) or did not have an SI but failed the SI goal (line 5).

**Table 2.2 and Tables 2.2.x PMA 180 Day Supplements MDUFA Decision Performance Goals – Definitions**

#	Measure	Description
1	Supplements filed	Number of 180 day PMA supplements received in this fiscal year.
2	Non-MDUFA IV Decisions	Supplements received (line 1) and closed with a non-MDUFA IV decision (such as ABND, CONV, OTHR, RECL, WTDR, XPMA).
3	MDUFA IV Decisions	Supplements received (line 1) and closed with a MDUFA IV decision.
4	MDUFA IV Decisions Goal Met	Submissions with MDUFA IV decisions (line 3) made before or on the MDUFA goal due date.
5	Supplements pending MDUFA IV Decision	Number of supplements received (line 1) that do not have a MDUFA IV decision or a final decision.
6	Supplements pending MDUFA IV Decision Past Goal	Number of supplements pending MDUFA IV Decision (line 5) past goal. These supplements already failed the MDUFA IV review goal.
7	Current Performance Percent Goal Met	Number of supplements with MDUFA IV Decisions made on time (line 4) divided by the total number of supplements with MDUFA IV Decisions (line 3) and pending supplements that already failed the MDUFA goal (line 6).

**Table 2.3 and Tables 2.3.x PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable – Definitions**

#	Measure	Description
1	Number Received	Number of PMA 180 Day Supplements received in this fiscal year.
2	Number with MDUFA decision	Number supplements received (line 1) and closed with a MDUFA decision.
3	Number of Not Approvable	Number of supplements received (line 1) and closed with MDUFA decision of NOAP (Not Approvable).
4	Rate of Not Approvable	Number of Not Approvable (line 3) divided by Number with MDUFA decision (line2).

**Table 2.4 and Tables 2.4.x PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals – Definitions**

#	Measure	Description
1	Number of submissions that missed the goal	Number of 180 Day supplements, received in this fiscal year, with number FDA days to MDUFA IV decision exceeding number of goal days.
2	Mean FDA days for submissions that missed goal	Mean FDA days for supplements that missed the goal (line 1).
3	Mean industry days for submissions that missed goal	Mean industry days for supplements that missed the goal (line 1).

### Section 3 PMA Real Time Supplements

**Table 3.1 and Tables 3.1.x Real Time PMA Supplements MDUFA Performance Goals – Definitions**

#	Measure	Description
1	Supplements received	Number of Real Time PMA supplements that were received in this fiscal year.
2	Non-MDUFA IV Decisions	Supplements received in this fiscal year (line 1) and closed with a non-MDUFA IV decision (such as ABND, CONV, OTHR, RECL, WTDR, XPMA).
3	MDUFA IV Decisions	Supplements received in this fiscal year (line 1) and closed with a MDUFA IV decision.
4	MDUFA IV Decisions Goal Met	Submissions with MDUFA IV decisions (line 3) within goal.
5	Supplements pending MDUFA IV Decision	Number of supplements received in this fiscal year (line 1) that do not have a MDUFA IV decision and are not closed with a final decision.
6	Supplements pending MDUFA IV Decision Past Goal	Number of supplements pending MDUFA IV Decision (line 5) past goal. These supplements already failed the MDUFA IV review goal.
7	Current Performance Percent Goal Met	Number of supplements with MDUFA IV Decisions made on time (line 4) divided by the total number of supplements with MDUFA IV Decisions (line 3) and pending supplements that already failed the MDUFA goal (line 6).

**Table 3.2 and Tables 3.2.x Real Time PMA Supplements Performance Metrics – Rate of Not Approvable – Definitions**

#	Measure	Description
1	Number Received	Number of PMA Real Time Supplements received in this fiscal year.
2	Number with MDUFA decision	Number supplements received (line 1) and closed with a MDUFA decision.
3	Number of Not Approvable	Number of supplements received (line 1) and closed with MDUFA decision of NOAP (Not Approvable).
4	Rate of Not Approvable	Number of Not Approvable (line 3) divided by Number with MDUFA decision (line 2).



**Table 3.3 and Tables 3.3.x****Real Time PMA Supplements Performance Metrics – Submissions Missing Performance Goals – Definitions**

#	Measure	Description
1	Number of submissions that missed the goal	Number of Real Time Supplements, received in this fiscal year, that also have a MDUFA decision, with number of FDA days to MDUFA decision exceeding number of goal days.
2	Mean FDA days for submissions that missed goal	Mean FDA days for supplements that missed the goal (line 1).
3	Mean industry days for submissions that missed goal	Mean industry days for supplements that missed the goal (line 1).

## Section 5 PMA Annual Metrics and Goals

**Table 5.1 PMAs (All Review Tracks) Annual General Metrics – Definitions**

#	Measure	Description
1	Premarket Report Submissions	Number of PMA Original submissions, with Reprocessed flag set to "Yes", received in this fiscal year.
2	Original PMAs (Panel) – Breakthrough	Number of PMA Original submissions with Panel review requested and Breakthrough flag set to "Yes", received in this fiscal year.
3	Original PMAs (No Panel) – Breakthrough	Number of PMA Original submissions with no Panel review requested and Breakthrough flag set to "Yes", received in this fiscal year.
4	Original PMAs (Panel) – Non- Breakthrough	Number of PMA Original submissions with Panel review requested and Breakthrough flag set to "No" or not set (blank), received in this fiscal year.
5	Original PMAs (No Panel) – Non-Breakthrough	Number of PMA Original submissions with no Panel review requested and Breakthrough flag set to "No" or not set (blank), received in this fiscal year.
6	Panel Track Supplements (Panel) – Breakthrough	Number of PMA Panel Track Supplements with Panel review requested and Breakthrough flag set to "Yes", received in this fiscal year.
7	Panel Track Supplements (No Panel) – Breakthrough	Number of PMA Panel Track Supplements with no Panel review requested and Breakthrough flag set to "Yes", received in this fiscal year.
8	Panel Track Supplements (Panel) – Non-Breakthrough	Number of PMA Panel Track Supplements with Panel review requested and Breakthrough flag set to "No" or not set (blank), received in this fiscal year.
9	Panel Track Supplements (No Panel) – Non-Breakthrough	Number of PMA Panel Track Supplements with no Panel review requested and Breakthrough flag set to "No" or not set (blank), received in this fiscal year.
10	PMA Modules	Number of PMA Modules received with a valid eCopy or taken off eCopy hold in this fiscal year.
11	180-Day Supplements	Number of PMA 180-Day supplements received in this fiscal year.
12	Real-Time Supplements	Number of PMA Real-Time supplements received in this fiscal year.

**Table 5.2 PMA Originals and Panel Track Supplements Annual Shared Outcome Goal – Definitions**

#	Measure	Description
1	Number Filed	Total number of PMA Original and Panel Track Supplement submissions filed in this fiscal year.
2	Number with a decision (MDUFA or Non-MDUFA)	Number of submissions filed in this fiscal year (line 1) that were closed with either MUDFA or non-MDUFA decision.
3	% of FY closed	Number with a decision (line 2) divided by Number Filed (line 1).

**Table 5.3 PMA Originals and Panel Track Supplements Annual Shared Outcome Goal – Three-year Rolling Average Time to MDUFA Decision – Definitions**

#	Measure	Description
1	Number with MDUFA decision	Number of PMA submissions filed in this and two previous years that were closed with a MDUFA decision.
2	Number with MDUFA decision after trimming the upper and lower 5%	Number of PMA submissions filed in this and two previous years that were closed with a MDUFA decision (line 1) excluding 5% of submissions with the lowest number of Total Days to MDUFA IV decision and 5% of submissions with the highest number of Total Days to MDUFA IV decision.
3	Three-year Rolling Average Total Time to MDUFA decision	Average Total Time (FDA and Industry) for the three-year receipt cohort. Each of the three years has to be closed (95% of submissions must have a MDUFA decision) in order for this value to be calculated. If any of these three years is not closed, then this cell shall be left blank. The rolling average shall be calculated for submissions with MDUFA decision, excluding outliers (top and bottom 5%) – these submissions are counted on line 2. For FY 2011 and FY 2012 Total Time to MDUFA II (two) decision will be used.

## Section 6 510(k) MDUFA IV Performance (Quarterly Data Exclude Third Party Review)

**Table 6.1 and Tables 6.1.x 510(k) Acceptance Review Decision – Definitions**

#	Measure	Description
1	Number Received	Number of 510(k) submissions received in this fiscal year.
2	Closed before RTA action	Number Received (line 1) that were closed with a final decision before RTA action.
3	Number Accepted	Number Received (line 1) that received an "RTA Accepted" (RTAA) decision in the first RTA review cycle.
4	Number Without a RTA Review and > 15 days since Date Received	Number Received (line 1) that received a "Did not perform RTA" (RTAN, RTAS or RTAW) decision in the first RTA review cycle. An RTAN decision is automatically recorded by CTS at the end of day 15 of RTA review, if no other RTA decision is made. This RTA decision means that the 510(k) is deemed accepted.
5	Number Without a RTA Review and <= 15 days since Date Received	Number Received (line 1) that are still in the first RTA review cycle and have not yet reached the 15 <sup>th</sup> day of that cycle..
6	Number Not Accepted	Number of submissions received in this fiscal year (line 1) that got a "Not Accepted" decision in the first RTA review cycle.
7	Rate of Submissions Not Accepted for Review	Number Not Accepted (line 6) expressed as a percentage of the sum of the Number Accepted (line 3), Number of RTA Review not done and > 15 days since Date Received (line 4), and Number Not Accepted (line 6).

**Table 6.2 and Tables 6.2.x 510(k) Substantive Interaction Performance Goal – Definitions**

#	Measure	Description
1	Eligible for SI	Number of 510(k) submissions accepted or deemed accepted via the RTA process as of quarter end date (RTAA, RTAN, RTAW or RTAS).
2	Deleted or Withdrawn Prior to SI	Number of 510(k)s that were Eligible for SI (line 1) but with the following Non-MDUFA decisions made as of the quarter end date and before any SI action: WTDR, DELE.
3	SI Within 60 FDA days	Number of submissions with SI action within 60 FDA days.
4	SI Over 60 FDA days	Number of submissions with SI action taken in more than 60 FDA days.
5	SI Pending within 60 FDA days	Submissions that are awaiting SI and where 60 days have not yet elapsed.
6	SI Pending over 60 FDA days	Submissions that are under review over 60 FDA days and that do not have an SI.
7	510(k)s NSE Without SI	Number of 510(k) submissions that are closed with an NSE decision (and did not have an SI).
8	Current SI Performance Percent within 60 FDA days	Number of submissions with SI within 60 FDA days (line 3) expressed as a percentage of the sum of the number of submissions that either had an SI (line 3 and line 4), the number of submissions that received an SI after 60 days had elapsed (line 6), and the number of submissions that were found NSE without first receiving an SI (line 7).

**Table 6.3 and Tables 6.3.x****510(k) Substantive Interaction Metric – Time to Substantive Interaction – Definitions**

#	Measure	Description
1	Number of Substantive Interaction	Number of 510(k) submissions accepted in this fiscal year that had an SI.
2	Average number of FDA days to Substantive Interaction	Average number of FDA days to substantive interaction across all 510(k) submissions with SI (line 1).
3	20 <sup>th</sup> Percentile FDA days to Substantive Interaction	20 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
4	40 <sup>th</sup> Percentile FDA days to Substantive Interaction	40 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
5	60 <sup>th</sup> Percentile FDA days to Substantive Interaction	60 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
6	80 <sup>th</sup> Percentile FDA days to Substantive Interaction	80 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
7	Maximum FDA days to Substantive Interaction	Maximum FDA days (100 <sup>th</sup> percentile) to Substantive Interaction for submissions with SI (line 1).

**Tables 6.4 and Tables 6.4.x 510(k) MDUFA Decision Performance Goal – Definitions**

#	Measure	Description
1	510(k)s Accepted	Number of 510(k) submissions accepted in this fiscal year.
2	Non-MDUFA IV Decisions	Number of submissions accepted (line 1) and closed with a non-MDUFA IV decision (not SE or NSE).
3	MDUFA IV Decision (SE/NSE)	Number of submissions accepted (line 1) and closed with a MDUFA IV decision (SE or NSE).
4	MDUFA IV Decision within 90 FDA Days	Number of submissions with MDUFA IV decision (line 3) made within 90 FDA days.
5	510(k)s Pending MDUFA IV Decision	Number of submissions accepted (line 1) and still under review.
6	510(k) Pending MDUFA IV Decision Over 90 FDA Days	Number of submissions pending MDUFA IV Decision (line 5) for more than 90 FDA Days. These submissions already failed the MDUFA IV review goal.
7	Current Performance Percent Within 90 FDA Days	Number of submissions with MDUFA IV Decisions within 90 FDA Days (line 4) expressed as a percentage of the sum of the number of submissions with MDUFA IV Decisions (line 3) and pending submissions that already failed the MDUFA goal (line 6).

**Table 6.5 and Tables 6.5.x 510(k) Time to MDUFA IV Decision – Definitions**

#	Measure	Description
1	Average Review Cycles	Average number of review cycles (after submission is accepted for review) for 510(k)s with a MDUFA decision (line 2).
2	Number with MDUFA IV Decision	Number of submissions accepted in this fiscal year that had a MDUFA decision.
	Days to MDUFA IV Decision	Table shall show Average Days to MDUFA IV decision as well as quintiles (20 <sup>th</sup> , 40 <sup>th</sup> , 60 <sup>th</sup> , 80 <sup>th</sup> percentiles) and the Maximum Days (100 <sup>th</sup> percentile) for FDA days, Industry days, and Total days to MDUFA IV decision.

**Table 6.6 and Tables 6.6.x****510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decision – Definitions**

#	Measure	Description
1	510(k) Accepted	Number of 510(k) submissions accepted in this fiscal year.
2	Number with MDUFA IV Decision	Number submissions accepted (line 1) that had a MDUFA decision.
3	Number of SE Decision	Number of submissions accepted (line 1) that had an SE MDUFA decision.
4	Number of NSE Decision	Number of submissions accepted (line 1) that had an NSE MDUFA decision.
5	Number of Withdrawal	Number of submissions accepted (line 1) and closed with Withdrawal final decision.
6	Number Deleted	Number of submissions accepted (line 1) and closed with Delete final decision.
7	Rate of SE Decision	Number of SE decisions (line 3) expressed as a percentage of the Number with MDUFA decision (line 2).
8	Rate of NSE Decision	Number of NSE decisions (line 4) expressed as a percentage of the Number with MDUFA decision (line 2).
9	Rate of Withdrawal	Number of Withdrawals (line 5) expressed as a percentage of the Number Accepted (line 1).
10	Rate of Deleted	Number of Deleted (line 6) expressed as a percentage of the by Number Accepted (line 1).

**Table 6.7 and Tables 6.7.x****510(k) Performance Metric – Submissions Missing Performance Goal – Definitions**

#	Measure	Description
1	Number of Submissions that Missed the Goal	Number of 510(k) submissions accepted in this fiscal year that had a MDUFA decision with more than 90 FDA days.
2	Mean FDA Days for Submissions that Missed the Goal	Mean FDA days for submissions that missed the goal (line 1).
3	Mean Industry Days for Submissions that missed goal	Mean industry days for submissions that missed the goal (line 1).



**Tables 6.8 and Tables 6.8.x LDT 510(k) MDUFA IV Decision Metric – Definitions**

#	Measure	Description
1	510(k)s accepted	Number of 510(k) submissions for LDTs accepted in this fiscal year.
2	Non-MDUFA IV Decision	Number of LDT submissions accepted (line 1) and closed with a non-MDUFA IV decision (not SE or NSE).
3	MDUFA IV Decision (SE/NSE)	Number of LDT submissions accepted (line 1) and closed with a MDUFA IV decision (SE or NSE).
4	MDUFA IV Decision within 90 FDA Days	Number of LDT submissions with MDUFA IV decisions (line 3) made within 90 FDA days.
5	510(k)s pending MDUFA IV Decision	Number of submissions accepted (line 1) and still under review.
6	510(k) pending MDUFA IV Decision over 90 FDA days	Number of LDT submissions pending MDUFA IV Decision (line 5) for more than 90 FDA Days. These submissions already failed the MDUFA IV review goal.
7	Current Performance Percent within 90 FDA Days	Number of LDT submissions with MDUFA IV Decisions within 90 FDA Days (line 4) divided by the total number of LDT submissions with MDUFA IV Decisions (line 3) and pending LDT submissions that already failed the MDUFA goal (line 6).

**Tables 6.9 and Tables 6.9.x Conventional IVD (Non-LDT) 510(k) MDUFA IV Decision Metric – Definitions**

#	Measure	Description
1	510(k)s Accepted	Number of 510(k) submissions for non-LDT IVDs accepted in this fiscal year.
2	Non-MDUFA IV Decision	Number of non-LDT IVD submissions accepted (line 1) and closed with a non-MDUFA IV decision (not SE or NSE).
3	MDUFA IV Decision (SE/NSE)	Number of non-LDT IVD submissions accepted (line 1) and closed with a MDUFA IV decision (SE or NSE).
4	MDUFA IV Decision within 90 FDA Days	Number of non-LDT IVD submissions with MDUFA IV decisions (line 3) made within 90 FDA days.
5	510(k)s Pending MDUFA IV Decision	Number of non-LDT IVD submissions accepted (line 1) and still under review.
6	510(k) Pending MDUFA IV Decision Over 90 FDA Days	Number of non-LDT IVD submissions pending MDUFA IV Decision (line 5) for more than 90 FDA Days. These submissions already failed the MDUFA IV review goal.
7	Current Performance Percent within 90 FDA Days	Number of non-LDT IVD submissions with MDUFA IV Decisions within 90 FDA Days (line 4) divided by the total number of non-LDT IVD submissions with MDUFA IV Decisions (line 3) and pending non-LDT IVD submissions that already failed the MDUFA goal (line 6).

## Section 7 510(k) Annual General Metrics (Annual data includes Third Party reviews)

**Table 7.1 CDRH - 510(k) Annual General Metrics – 510(k)s Received by Type – Definitions**

#	Measure	Description
1	Number Accepted	Total number of 510(k) submissions accepted in this fiscal year. This metric includes Third Party 510(k) submissions.
2	Number of Traditional submissions	Number of Traditional Non-Third Party 510(k) submissions accepted in this fiscal year.
3	Number of Special submissions	Number of Special Non-Third Party 510(k) submissions accepted in this fiscal year.
4	Number of Abbreviated submissions	Number of Abbreviated Non-Third Party 510(k) submissions accepted in this fiscal year.
5	Average number of days to Accept / Refuse to Accept	Average number of days in the first RTA review cycle for Non-Third Party 510(k) submissions.
6	Number of Third Party submissions	Number of Third Party 510(k) submissions received in this fiscal year.

**Table 7.2 CDRH - 510(k) Annual Shared Outcome Goal – Definitions**

#	Measure	Description
1	Number Accepted	Total number of 510(k) submissions accepted in this fiscal year. This metric includes Third Party 510(k) submissions..
2	Currently Under Review	Number of 510(k) submissions accepted (line 1) that are still under review (no final decision yet).
3	Number with Non-MDUFA IV decision	Number of 510(k) submissions accepted (line 1) that were closed with a Non-MDUFA decision.
4	Number with MDUFA IV Decision	Number of 510(k) submissions accepted (line 1) that had a MDUFA IV decision.
5	Percent of cohort closed	Number with MDUFA decision (line 4) expressed as a percentage of the sum of Number Under Review (line 2) and Number with MDUFA Decision (line 4).
6	Number with MDUFA IV decision after trimming the upper and lower 2%	Number of 510(k) submissions with MDUFA IV Decision (line 4) excluding the 2% of submissions with the lowest number of Total Days to MDUFA IV decision and the 2% of submissions with the highest number of Total Days to MDUFA IV decision.
7	Average Total Time to MDUFA IV decision	Average Total Time (FDA and Industry) to MDUFA decision, where the denominator is the trimmed number with MDUFA decision (line 6). If the cohort has not yet reached 99% closure, "N/A" shall be displayed instead.

**Table 7.3 CDRH - 510(k) Third Party Performance – Definitions**

#	Measure	Description
1	Number of Third Party Submissions	Number of Third Party 510(k) submissions received in this fiscal year.
2	90 <sup>th</sup> Percentile FDA Days to MDUFA IV Decision	The 90 <sup>th</sup> percentile of FDA days to MDUFA IV decision on 3 <sup>rd</sup> Party 510(k) submissions received in this fiscal year

## Section 8 De Novo MDUFA IV Performance

**Table 8.1 and Tables 8.1.x De Novo Acceptance Review Decision\* - Definitions**

#	Measure	Description
1	Number Received	Number of De Novo submissions received in this fiscal year.
2	Closed before RTA action	Number Received (line 1) that were closed with a final decision before RTA action.
3	Number Accepted First RTA Cycle	Number Received (line 1) that got "RTA Accepted" (RTAA) decision in the first RTA review cycle entered by reviewer.
4	Number Without a RTA Review and > 15 days since Date Received	Number Received (line 1) that got "Did not perform RTA" (RTAN ) decision in the first RTA review cycle automatically recorded by CTS at the end of day 15 of RTA review. These RTA reviews deemed approved.
5	Number Without a RTA Review and <= 15 days since Date Received	Number Received (line 1) that are still in the first RTA review cycle.
6	Number Not Accepted	Number of submissions received in this fiscal year (line 1) that got a "Not Accepted" decision in the first RTA review cycle.
7	Rate of Submissions Not Accepted for Review	Number Not Accepted (line 6) expressed as a percentage the sum of the total of Number Accepted (line 3), Number of RTA Review not done and > 15 days since Date Received (line 4), and Number Not Accepted (line 6).

\*RTA will be implemented when the guidance, including the submission checklist, is finalized.

**Tables 8.2 and Tables 8.2.x De Novo MDUFA IV Decision Performance Goals – Definitions**

#	Measure	Description
1	De Novos Accepted	Number of De Novo submissions accepted in this fiscal year.
2	Non-MDUFA IV Decisions	Number of submissions accepted (line 1) and closed with a non-MDUFA IV decision (not Granted/Declined, Withdrawn or Deleted).
3	MDUFA IV Decisions	Number of submissions accepted (line 1) and closed with a MDUFA IV decision (Granted/Declined, Withdrawn or Deleted).
4	MDUFA IV Decisions within 150 FDA Days	Number of submissions with MDUFA IV decisions (line 3) made within 150 FDA days.
5	De Novos pending MDUFA IV Decision	Number of submissions accepted (line 1) and still under review.
6	De Novos pending MDUFA IV Decision over 150 FDA days	Number of submissions pending MDUFA IV Decision (line 5) for more than 150 FDA Days. These submissions already failed the MDUFA IV review goal.
7	Current Performance Percent within 150 FDA Days	Number of submissions with MDUFA IV Decisions within 150 FDA Days (line 4) expressed as a percentage of the sum of the total number of submissions with MDUFA IV Decisions (line 3) and pending submissions that already failed the MDUFA goal (line 6).

**Table 8.3 and Tables 8.3.x De Novo Time to MDUFA IV Decision – Definitions**

#	Measure	Description
1	Average Review Cycles	Average number of review cycles (after submission is accepted for review) for De Novos with a MDUFA IV decision (line 2).
2	Number with MDUFA IV Decision	Number of submissions accepted in this fiscal year that had a MDUFA IV decision.
	Days to MDUFA IV Decision	Table shall show Average Days to MDUFA IV decision as well as quintiles (20 <sup>th</sup> , 40 <sup>th</sup> , 60 <sup>th</sup> , 80 <sup>th</sup> percentiles) and the Maximum Days (100 <sup>th</sup> percentile) for FDA days, Industry days, and Total days to MDUFA IV decision.

**Table 8.4 and Tables 8.4.x****De Novo Performance Metrics – Rate of Grant, Decline, Withdrawal and Delete Decisions – Definitions**

#	Measure	Description
1	De Novos Accepted	Number of De Novos submissions accepted in this fiscal year.
2	Number with MDUFA IV Decisions	Number submissions accepted (line 1) that had a MDUFA IV decision.
3	Number with Granted Decisions	Number of submissions accepted (line 1) that had a Granted MDUFA IV decision.
4	Number with Declined Decisions	Number of submissions accepted (line 1) that had a Declined MDUFA IV decision.
5	Number of Withdrawals	Number of submissions accepted (line 1) that had a Withdrawn MDUFA IV decision.
6	Number of Deleted	Number of submissions accepted (line 1) and closed that had a Deleted MDUFA IV decision
7	Rate of Granted Decisions	Number of Granted decisions (line 3) divided by Number with MDUFA IV decision (line 2).
8	Rate of Declined Decisions	Number of Declined decisions (line 4) divided by Number with MDUFA IV decision (line 2).
9	Rate of Withdrawals	Number of Withdrawals (line 5) divided by Number with MDUFA IV decision (line 2).
10	Rate of Deleted	Number of Deleted (line 6) divided by Number with MDUFA IV decision (line 2).

**Table 8.5 and Tables 8.5.x****De Novo Performance Metrics – Submissions Missing Performance Goals – Definitions**

#	Measure	Description
1	Number of Submissions that Mssed the Goal	Number of De Novo submissions accepted in this fiscal year that had a MDUFA IV decision with more than 150 FDA days.
2	Mean FDA days for submissions that missed goal	Mean FDA days for submissions that missed the goal (line 1).
3	Mean Industry Days for Submissions that Missed the Goal	Mean industry days for submissions that missed the goal (line 1).

**Tables 8.6 and Tables 8.6.x LDT De Novo MDUFA IV Decision Metrics – Definitions**

#	Measure	Description
1	De Novos accepted	Number of De Novo submissions for LDTs accepted in this fiscal year.
2	Non-MDUFA IV Decisions	Number of LDT submissions accepted (line 1) and closed with a non-MDUFA IV decision (not Granted, Declined, Withdrawn or Deleted).
3	MDUFA IV Decisions	Number of LDT submissions accepted (line 1) and closed with a MDUFA IV decision (Granted, Declined, Withdrawn or Deleted).
4	MDUFA IV Decisions Within 150 FDA Days	Number of LDT submissions with MDUFA IV decisions (line 3) made within 150 FDA days.
5	De Novos Pending MDUFA IV Decision	Number of LDT submissions accepted (line 1) and still under review.
6	De Novos Pending MDUFA IV Decision over 150 FDA days	Number of LDT submissions pending MDUFA IV Decision (line 5) for more than 150 FDA Days. These submissions already failed the MDUFA IV review goal.
7	Current Performance Percent within 150 FDA Days	Number of LDT submissions with MDUFA IV Decisions within 150 FDA Days (line 4) expressed as a percentage of the sum of the total number of LDT submissions with MDUFA IV Decisions (line 3) and pending LDT submissions that already failed the MDUFA goal (line 6).



**Tables 8.7 and Tables 8.7.x Conventional IVD (non-LDT) De Novo MDUFA IV Decision Metrics – Definitions**

#	Measure	Description
1	De Novos Accepted	Number of De Novo submissions for non-LDT IVDs accepted in this fiscal year.
2	Non-MDUFA IV Decisions	Number of non-LDT IVD submissions accepted (line 1) and closed with a non-MDUFA IV decision (not Granted, Declined, Withdrawn or Deleted).
3	MDUFA IV Decisions	Number of non-LDT IVD submissions accepted (line 1) and closed with a MDUFA IV decision (Granted, Declined, Withdrawn or Deleted).
4	MDUFA IV Decisions within 150 FDA Days	Number of non-LDT IVD submissions with MDUFA IV decisions (line 3) made within 150 FDA days.
5	De Novos Pending MDUFA IV Decision	Number of non-LDT IVD submissions accepted (line 1) and still under review.
6	De Novos Pending MDUFA IV Decision Over 150 FDA Days	Number of non-LDT IVD submissions pending MDUFA IV Decision (line 5) for more than 150 FDA Days. These submissions already failed the MDUFA IV review goal.
7	Current Performance Percent Within 150 FDA Days	Number of non-LDT IVD submissions with MDUFA IV Decisions within 150 FDA Days (line 4) expressed as a percentage of the sum of the total number of non-LDT IVD submissions with MDUFA IV Decisions (line 3) and pending non-LDT IVD submissions that already failed the MDUFA goal (line 6).

**Section 8 Annual Metrics for De Novo Requests**

**Table 8.8 CDRH – Annual General Metric Report for De Novo Requests - Definitions**

#	Measure	Description
1	Number Accepted First RTA Cycle	Number of De Novo submissions accepted in the first RTA cycle in this fiscal year as of the report cutoff date.
4	Average Number of Days to Accept/Refuse to Accept*	Average number of days in the first RTA review cycle De Novo submissions..

\*RTA will be implemented when the guidance, including the submission checklist, is finalized.

## Section 9 Pre-Submissions

**Table 9.1 and Tables 9.1.x Pre-Sub Acceptance Review Decision – Definitions**

#	Measure	Description
1	Number Received	Number of Pre-Subs submissions received in this fiscal year.
2	Closed before RTA Action	Number Received (line 1) that were closed with a final decision before RTA action.
3	Number Accepted First RTA Cycle	Number Received (line 1) that had "RTA Accepted" (RTAA) decision in the first RTA review cycle entered by reviewer.
4	Number Without a RTA Review and > 15 days Since Date Received	Number Received (line 1) that had "Did not perform RTA" (RTAN) decision in the first RTA review cycle automatically recorded by CTS at the end of day 15 of RTA review.
5	Number Without a RTA Review and <= 15 days Since Date Received	Number Received (line 1) that are still in the first RTA review cycle at the quarter end date.
6	Number Not Accepted	Number of submissions received in this fiscal year (line 1) that had "Refuse to accept" (RTA1) decision in the first RTA review cycle.
7	Rate of Submissions Not Accepted for Review	Number Not Accepted (line 6) divided by the total of Number Accepted (line 3), Number of RTA Review not done and > 15 days since Date Received (line 4), and Number Not Accepted (line 6).

**Table 9.2 and Tables 9.2.x Pre-Submissions Performance Metrics – Definitions**

#	Measure	Description
1	Written Feedback Sent	Number of Pre-Subs for which Written Feedback was sent to the sponsor by the reviewer entering a MDUFA IV Decision of either "Email Reply" (EMAL) or "Email Feedback Sent Before Meeting" (EMFB) in CTS. EMAL is used for Pre-Subs where there is no meeting requested. EMFB is used for Pre-Subs when a meeting is requested.
2	Written Feedback Provided Within MDUFA IV Goal	Number of Pre-Subs that had Written Feedback sent (line 1) by Day 70 (for Pre-Subs without a meeting request), or by 5 Days before the Meeting Date or Day 70, whichever is sooner (for Pre-Subs with a meeting request).

**Table 9.3 and Tables 9.3.x Pre-Sub Time to MDUFA IV Metrics – Definitions**

#	Measure	Description
1	Written Feedback Sent	Number of Pre-Subs for which Written Feedback was sent to the sponsor by the reviewer entering a MDUFA IV Decision of either “Email Reply” (EMAL) or “Email Feedback Sent Before Meeting” (EMFB) EMAL is used for Pre-Subs where there is no meeting requested. EMFB is used for Pre-Subs when a meeting is requested.
2	Average FDA Days to Written Feedback	Average number of days from the start of FDA review to MDUFA IV Decision (EMAL or EMFB) for Pre-Subs with Written Feedback sent (line 1).
3	20 <sup>th</sup> Percentile FDA Days to Written Feedback	20 <sup>th</sup> percentile FDA days to Written Feedback for Pre-Subs with MDUFA IV Decision EMAL or EMFB (line 1).
4	40 <sup>th</sup> Percentile FDA Days to Written Feedback	40 <sup>th</sup> percentile FDA days to Written Feedback for Pre-Subs with MDUFA IV Decision EMAL or EMFB (line 1).
5	60 <sup>th</sup> Percentile FDA Days to Written Feedback	60 <sup>th</sup> percentile FDA days to Written Feedback for Pre-Subs with MDUFA IV Decision EMAL or EMFB (line 1).
6	80 <sup>th</sup> Percentile FDA Days to Written Feedback	80 <sup>th</sup> percentile FDA days to Written Feedback for Pre-Subs with MDUFA IV Decision EMAL or EMFB (line 1).
7	Maximum FDA Days to Written Feedback	Maximum FDA days (100 <sup>th</sup> percentile) to Written Feedback for Pre-Subs with MDUFA IV Decision EMAL or EMFB (line 1).

**Table 9.4 and Tables 9.4.x Pre-Submissions Performance Metrics Meeting Scheduling-Definitions**

#	Measure	Description
1	Meetings Not Scheduled by Day 30	Number of Pre-Subs for which a Meeting was Requested and a Meeting Date was not confirmed by the reviewer in CTS by day 30.
2	Average Days to Scheduling for Meetings Scheduled After Day 30	Average days to confirming a Meeting Date in CTS for Meetings not scheduled by Day 30 (line 1).

**Table 9.5 and Tables 9.5.x Pre-Submissions Performance Metrics Meeting Minutes- Definitions**

#	Measure	Description
1	Meetings Held	Number of Pre-Sub Meeting Requests for which a Meeting was held and reviewer closed the submission in CTS by the quarter end date.
2	Meeting Minutes Submitted Within 15 Days of Meeting	Number of Pre-Sub Meeting Requests with Meetings held (line 1), for which Meeting Minutes were received within 15 days after Meeting Date.
3	Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	Number of Pre-Sub Meeting Requests with Meetings held (line 1), for which Meeting Minutes have not been received and it is still under 15 days since meeting (as of end of quarter).
4	Meeting Minutes Past 15 Days of Meeting	Number of Pre-Sub Meeting Requests with Meetings held (line 1), for which Meeting Minutes were received more than 15 days after Meeting Date.
5	Meeting Minutes Not Submitted and >15 Days Since Meeting	Number of Pre-Sub Meeting Requests with Meetings held (line 1), for which Meeting Minutes have not been received and more than 15 days have passed since the Meeting Date (as of end of quarter).
6	Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	Number of Meeting Minutes received within 15 days (line 2) divided by the total of Number of Meeting Minutes received within 15 days (line 2), Number of Meeting Minutes received past 15 days (line 4), and Number of Meeting Minutes which have not been received and >15 days since Meeting Date (line 5).

**Section 10 IDE Performance Metrics**

**Table 10.1 IDE Performance Metrics**

#	Measure	Description
1	Number of IDEs received	Number of IDEs received in the fiscal year.
2	Average number of cycles to approval or conditional approval of the IDE	The average number of cycles including the original submission and amendments that were submitted prior to the approval or conditional approval of an IDE.
3	Average number of amendments prior to approval or conditional approval of the IDE	The average number of amendments, to include only those amendments that were submitted to address deficiencies in the disapproval letter.

## Section 11 CLIA Waiver Annual Metrics

**Table 11.1 CLIA Waiver Substantive Interaction Performance Goals – Definitions**

#	Measure	Description
1	Eligible for SI	Number of CLIA Waiver by Applications that were accepted in this fiscal year.
2	Withdrawn prior to SI	Number of submissions that were Withdrawn within 90 FDA days.
3	SI within 90 FDA days	Number of submissions with SI action within 90 FDA days.
4	SI over 90 FDA days	Number of submissions with SI action taken in more than 90 FDA days.
5	SI pending within 90 FDA days	Submissions that are awaiting SI and where 90 days have not yet elapsed.
6	SI pending over 90 FDA days	Submissions that have been under review over 90 FDA days and that do not have an SI.
7	Denial without SI	Number of submissions closed with a Denial decision and that did not have an SI prior.
8	Current SI Performance Percent within 90 FDA days	Number of submissions with SI within goal (line 3) divided by the total number of submissions that either had an SI (line 3 and line 4) or did not have an SI but failed the SI goal (line 6 and line 7).

**Table 11.2 CLIA Waiver Substantive Interaction Metrics – Time to Substantive Interaction – Definitions**

#	Measure	Description
1	Number of Substantive Interactions	Number of CLIA Waiver by Applications accepted in this fiscal year that had an SI.
2	Average number of FDA days to Substantive Interaction	Average number of FDA days to SI across all CLIA Waivers with SI (line 1).
3	20 <sup>th</sup> Percentile FDA days to Substantive Interaction	20 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
4	40 <sup>th</sup> Percentile FDA days to Substantive Interaction	40 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
5	60 <sup>th</sup> Percentile FDA days to Substantive Interaction	60 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
6	80 <sup>th</sup> Percentile FDA days to Substantive Interaction	80 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
7	Maximum FDA days to Substantive Interaction	Maximum FDA days (100 <sup>th</sup> percentile) to Substantive Interaction for submissions with SI (line 1).

**Table 11.3 CLIA Waiver (without Panel Review) MDUFA IV Decision Performance Goals – Definitions**

#	Measure	Description
1	Eligible for MDUFA IV Decisions	Number of CLIA Waiver by Applications that were accepted in this fiscal year, and did not have a panel review.
2	Non-MDUFA IV Decisions	Number of submissions closed with a non-MDUFA IV decision (not Approved, Denied, or Withdrawn).
3	MDUFA IV Decisions	Number of submissions closed with a MDUFA IV decision (Approved, Denied, or Withdrawn).
4	MDUFA IV Decisions within 150 FDA Days	Number of submissions with MDUFA IV decisions made within 150 FDA days.
5	CLIA Waiver Applications pending MDUFA IV Decision	Number of submissions still under review.
6	CLIA Waiver Applications pending MDUFA IV Decision over 150 FDA days	Number of submissions pending MDUFA IV Decision for more than 150 FDA days. These submissions already failed the MDUFA IV Decision goal.
7	Current Performance Percent within 150 FDA Days	Number of submissions with MDUFA IV Decisions within 150 FDA days (line 4) divided by the total number of submissions that either had MDUFA IV decisions (line 3) or that already failed the MDUFA IV Decision goal (line 6).

**Table 11.4 CLIA Waiver (with Panel Review) MDUFA IV Decision Performance Goals) – Definitions**

#	Measure	Description
1	Eligible for MDUFA IV Decisions	Number of CLIA Waiver by Applications that were accepted in this fiscal year, and had a panel review.
2	Non-MDUFA IV Decisions	Number of submissions closed with a non-MDUFA IV decision (not Approved, Denied, or Withdrawn).
3	MDUFA IV Decisions	Number of submissions closed with a MDUFA IV decision (Approved, Denied, or Withdrawn).
4	MDUFA IV Decisions within 320 FDA Days	Number of submissions with MDUFA IV decisions made within 320 FDA days.
5	CLIA Waiver Applications pending MDUFA IV Decision	Number of submissions still under review.
6	CLIA Waiver Applications pending MDUFA IV Decision over 320 FDA days	Number of submissions pending MDUFA IV Decision for more than 320 FDA days. These submissions already failed the MDUFA IV Decision goal.
7	Current Performance Percent within 320 FDA Days	Number of submissions with MDUFA IV Decisions within 320 FDA days (line 4) divided by the total number of submissions that either had MDUFA IV decisions (line 3) or that already failed the MDUFA IV Decision goal (line 6).

**Table 11.5 CLIA Waiver (without Panel Review) Time to MDUFA IV Decision – Definitions**

#	Measure	Description
1	Number with MDUFA IV Decision	Number of submissions accepted in this fiscal year that had a MDUFA IV decision (Approved, Denied, or Withdrawn), and did not have a panel review.
	Days to MDUFA IV Decision	Table shall show Average Days to MDUFA IV decision as well as quintiles (20 <sup>th</sup> , 40 <sup>th</sup> , 60 <sup>th</sup> , 80 <sup>th</sup> percentiles) and the Maximum Days (100 <sup>th</sup> percentile) for FDA days, Industry days, and Total days.

**Table 11.6 CLIA Waiver (with Panel Review) Time to MDUFA IV Decision - Definitions**

#	Measure	Description
1	Number with MDUFA IV Decision	Number of submissions accepted in this fiscal year that had a MDUFA IV decision (Approved, Denied, or Withdrawn), and had a panel review.
	Days to MDUFA IV Decision	Table shall show Average Days to MDUFA IV decision as well as quintiles (20 <sup>th</sup> , 40 <sup>th</sup> , 60 <sup>th</sup> , 80 <sup>th</sup> percentiles) and the Maximum Days (100 <sup>th</sup> percentile) for FDA days, Industry days, and Total days.



## Section 12 Dual 510(k) and CLIA Waiver Annual Metrics

**Table 12.1 Dual 510(k) and CLIA Waiver Substantive Interaction Performance Goals – Definitions**

#	Measure	Description
1	Eligible for SI	Number of Dual 510(k) and CLIA Waiver by Applications with 510(k) RTA review accepted in this fiscal year.
2	Withdrawn prior to SI	Number of submissions that were Withdrawn prior to 90 days.
3	SI within 90 FDA days	Number of submissions with SI action within 90 FDA days.
4	SI over 90 FDA days	Number of submissions with SI action taken in more than 90 FDA days.
5	SI pending within 90 FDA days	Submissions that are awaiting SI and where 90 days have not yet elapsed.
6	SI pending over 90 FDA days	Submissions that have been under review over 90 FDA days and that do not have an SI.
7	Denial without SI	Number of submissions closed with a Denial decision and that did not have an SI prior.
8	Current SI Performance Percent within 90 FDA days	Number of submissions with SI within goal (line 3) divided by the total number of submissions that either had an SI (line 3 and line 4) or did not have an SI but failed the SI goal (line 6 and line 7).

**Table 12.2 Dual 510(k) and CLIA Waiver Substantive Interaction Metrics – Time to Substantive Interaction – Definitions**

#	Measure	Description
1	Number of Substantive Interactions	Number of Dual 510(k) and CLIA Waiver by Applications accepted in this fiscal year that had an SI
2	Average number of FDA days to Substantive Interaction	Average number of FDA days to SI across all Dual 510(k) and CLIA Waivers with SI (line 1).
3	20 <sup>th</sup> Percentile FDA days to Substantive Interaction	20 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
4	40 <sup>th</sup> Percentile FDA days to Substantive Interaction	40 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
5	60 <sup>th</sup> Percentile FDA days to Substantive Interaction	60 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
6	80 <sup>th</sup> Percentile FDA days to Substantive Interaction	80 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
7	Maximum FDA days to Substantive Interaction	Maximum FDA days (100 <sup>th</sup> percentile) to Substantive Interaction for submissions with SI (line 1).

**Table 12.3 Dual 510(k) and CLIA Waiver (without panel review) MDUFA IV Decision Performance Goals – Definitions**

#	Measure	Description
1	Eligible for MDUFA IV Decision	Number of Dual 510(k) and CLIA Waiver by Applications that were accepted in this fiscal year, and did not have a panel review.
2	Non-MDUFA IV Decisions	Number of submissions closed with non-MDUFA IV decisions.
3	MDUFA IV Decisions	Number of submissions closed with MDUFA IV decisions.
4	MDUFA IV Decisions within 180 FDA Days	Number of submissions with MDUFA IV decisions made within 180 FDA days.
5	Dual 510(k) and CLIA Waiver Applications pending MDUFA IV Decision	Number of submissions still under review.
6	Dual 510(k) and CLIA Waiver Applications pending MDUFA IV Decision over 180 FDA days	Number of submissions pending MDUFA IV Decision for more than 180 FDA days. These submissions already failed the MDUFA IV Decision goal.
7	Current Performance Percent within 180 FDA Days	Number of submissions with MDUFA IV Decisions within 180 FDA days (line 4) divided by the total number of submissions that either had MDUFA IV decisions (line 3) or that already failed the MDUFA IV Decision goal (line 6).

**Table 12.4 Dual 510(k) and CLIA Waiver (with panel review) MDUFA IV Decision Performance Goals – Definitions**

#	Measure	Description
1	Eligible for MDUFA IV Decision	Number of Dual 510(k) and CLIA Waiver by Applications that were accepted in this fiscal year, and had a panel review.
2	Non-MDUFA IV Decisions	Number of submissions closed with non-MDUFA IV decisions.
3	MDUFA IV Decisions	Number of submissions closed with MDUFA IV decisions.
4	MDUFA IV Decisions within 320FDA Days	Number of submissions with MDUFA IV decisions made within 320 FDA days.
5	Dual 510(k) and CLIA Waiver Applications pending MDUFA IV Decision	Number of submissions still under review.
6	Dual 510(k) and CLIA Waiver Applications pending MDUFA IV Decision over 320 FDA days	Number of submissions pending MDUFA IV Decision for more than 320 FDA days. These submissions already failed the MDUFA IV Decision goal.
7	Current Performance Percent within 320 FDA Days	Number of submissions with MDUFA IV Decisions within 320 FDA days (line 4) divided by the total number of submissions that either had MDUFA IV decisions (line 3) or that already failed the MDUFA IV Decision goal (line 6).

**Table 12.5 Dual 510(k) and CLIA Waiver (without panel review) Time to MDUFA IV Decision – Definitions**

#	Measure	Description
1	Number with MDUFA IV Decision	Number of submissions accepted in this fiscal year that had a MDUFA IV decision, and did not have a panel review.
	Days to MDUFA IV Decision	Table shall show Average Days to MDUFA IV decision as well as quintiles (20 <sup>th</sup> , 40 <sup>th</sup> , 60 <sup>th</sup> , 80 <sup>th</sup> percentiles) and the Maximum Days (100 <sup>th</sup> percentile) for FDA days, Industry days, and Total days.

**Table 12.6 Dual 510(k) and CLIA Waiver (with panel review) Time to MDUFA IV Decision – Definitions**

#	Measure	Description
1	Number with MDUFA IV Decision	Number of submissions accepted in this fiscal year that had a MDUFA IV decision, and had a panel review.
	Days to MDUFA IV Decision	Table shall show Average Days to MDUFA IV decision as well as quintiles (20 <sup>th</sup> , 40 <sup>th</sup> , 60 <sup>th</sup> , 80 <sup>th</sup> percentiles) and the Maximum Days (100 <sup>th</sup> percentile) for FDA days, Industry days, and Total days.

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**Quarterly Update on  
Medical Device Performance Goals  
----MDUFA IV CBER Performance Data ----  
Action through 31 Mar 2019**

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## Section 1 PMA Original and Panel-Track Supplements - Center Level Metric

Table 1.1 CBER - PMA Original and Panel-Track Supplements - Acceptance Review Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	3	1			
Closed Before RTA Action	0	0			
Number with Accepted RTA Review	1	0			
Number Without a RTA Review and > 15 Days Since Date Received	0	0			
Number Without a RTA Review and <= 15 Days Since Date Received	0	0			
Number Not Accepted for Filing Review	2	1			
Rate of Submissions Not Accepted for Filing Review	67%	100%			

Table 1.2 CBER - PMA Original and Panel-Track Supplements - Filing Review Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	3	1			
Number Accepted	1	0			
Completed RTF	3	1			
Number Not Filed	1	0			
Rate of Submissions Not Filed	33.33%	0.00%			

Table 1.3 CBER - PMA Original and Panel-Track Supplements Substantive Interaction

### Performance Goal

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	2	1			
SI Goal Met	2	1			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	0			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	100.00%	100.00%			

**Table 1.4 CBER - PMA Original and Panel-Track Supplements Substantive Interaction Metric - Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number of Substantive Interactions	2	1			
Average Number of FDA Days to Substantive Interaction	69.00	82.00			
20th Percentile FDA Days to Substantive Interaction	50.00	82.00			
40th Percentile FDA Days to Substantive Interaction	50.00	82.00			
60th Percentile FDA Days to Substantive Interaction	88.00	82.00			
80th Percentile FDA Days to Substantive Interaction	88.00	82.00			
Maximum FDA Days to Substantive Interaction	88.00	82.00			

**Table 1.5 CBER - PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>
Number of PMAs Filed	2	1			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	1	0			
MDUFA IV Decision Goal Met	1	0			
PMAs Pending MDUFA IV Decision	1	1			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100.00%	100.00%			

**Table 1.6 CBER - PMA Original and Panel-Track Supplements (with Panel Review) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>
Number of PMAs Filed	0	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	0	0			
MDUFA IV Decision Goal Met	0	0			
PMAs Pending MDUFA IV Decision	0	0			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	N/A	N/A			

**Table 1.7 CBER - PMA Original and Panel-Track Supplements (Without Panel Review)  
Performance Metric - Time to MDUFA IV Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number with MDUFA IV Decision	1	0			
<b>Average FDA Days to MDUFA IV Decision</b>	156.00	0.00			
20th Percentile FDA Days to MDUFA IV Decision	156.00	0.00			
40th Percentile FDA Days to MDUFA IV Decision	156.00	0.00			
60th Percentile FDA Days to MDUFA IV Decision	156.00	0.00			
80th Percentile FDA Days to MDUFA IV Decision	156.00	0.00			
Maximum FDA Days to MDUFA IV Decision	156.00	0.00			
<b>Average Industry Days to MDUFA IV Decision</b>	105.00	0.00			
20th Percentile Industry Days to MDUFA IV Decision	105.00	0.00			
40th Percentile Industry Days to MDUFA IV Decision	105.00	0.00			
60th Percentile Industry Days to MDUFA IV Decision	105.00	0.00			
80th Percentile Industry Days to MDUFA IV Decision	105.00	0.00			
Maximum Industry Days to MDUFA IV Decision	105.00	0.00			
<b>Average Total Days to MDUFA IV Decision</b>	261.00	0.00			
20th Percentile Total Days to MDUFA IV Decision	261.00	0.00			
40th Percentile Total Days to MDUFA IV Decision	261.00	0.00			
60th Percentile Total Days to MDUFA IV Decision	261.00	0.00			
80th Percentile Total Days to MDUFA IV Decision	261.00	0.00			
Maximum Total Days to MDUFA IV Decision	261.00	0.00			

**Table 1.8 CBER - PMA Original and Panel-Track Supplements (with Panel Review)  
Performance Metric - Time to MDUFA IV Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number with MDUFA IV Decision	0	0			
<b>Average FDA Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile FDA Days to MDUFA IV Decision	0	0			
40th Percentile FDA Days to MDUFA IV Decision	0	0			
60th Percentile FDA Days to MDUFA IV Decision	0	0			
80th Percentile FDA Days to MDUFA IV Decision	0	0			
Maximum FDA Days to MDUFA IV Decision	0	0			
<b>Average Industry Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	0	0			
80th Percentile Industry Days to MDUFA IV Decision	0	0			
Maximum Industry Days to MDUFA IV Decision	0	0			
<b>Average Total Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile Total Days to MDUFA IV Decision	0	0			
40th Percentile Total Days to MDUFA IV Decision	0	0			
60th Percentile Total Days to MDUFA IV Decision	0	0			
80th Percentile Total Days to MDUFA IV Decision	0	0			
Maximum Total Days to MDUFA IV Decision	0	0			

**Table 1.9 CBER - PMA Original and Panel-Track Supplements (Without Panel Review)**

**Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	2	1			
Number with MDUFA IV Decision	1	0			
Number of Withdrawal	0	0			
Number of Not Approvable	0	0			
Number of Deleted	0	0			
Rate of Withdrawal	N/A	N/A			
Rate of Not Approvable	N/A	N/A			

**Table 1.10 CBER - PMA Original and Panel-Track Supplements (with Panel Review)**

**Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	0	0			
Number With MDUFA IV Decision	0	0			
Number of Withdrawal	0	0			
Number of Not Approvable	0	0			
Number of Deleted	0	0			
Rate of Withdrawal	N/A	N/A			
Rate of Not Approvable	N/A	N/A			

**Table 1.11 CBER - PMA Original and Panel-Track Supplements (Without Panel Review)**

**Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00			
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00			

**Table 1.12 CBER - PMA Original and Panel-Track Supplements (with Panel Review)**

**Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00			
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00			

**Table 1.13 CBER - LDT PMA Original and Panel-Track Supplements Metric\***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days
Number of PMAs Filed	0	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	0	0			
MDUFA IV Decision Goal Met	0	0			
PMAs Pending MDUFA IV Decision	0	0			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	N/A	N/A			

\*Includes submission that went to panel

**Table 1.14 CBER - Conventional IVD (Non-LDT) PMA Original and Panel-Track Supplements**

**Metric\***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days
Number of PMAs Filed	1	1			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	0	0			
MDUFA IV Decision Goal Met	0	0			
PMAs Pending MDUFA IV Decision	1	1			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	0.00%	0.00%			

\*Includes submission that went to panel

## Section 2 PMA 180-Day Supplements - Center Level Metric

Table 2.1 CBER - PMA 180-Day Supplements Substantive Interaction Goal

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	8	1			
SI Goal Met	8	1			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	0			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	100%	100%			

Table 2.2 CBER - PMA 180-Day Supplements MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days
Supplements Received	8	1			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	5	0			
MDUFA IV Decision Goal Met	5	0			
Supplements Pending MDUFA IV Decision	3	1			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100.00%	N/A			

Table 2.3 CBER - PMA 180-Day Supplements Performance Metric - Rate of Not Approvable

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	8	1			
Number with MDUFA IV Decision	5	0			
Number of Not Approvable	0	0			
Rate of Not Approvable	0.00%	N/A			

Table 2.4 CBER - PMA 180-Day Supplements Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00			
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00			



### Section 3 PMA Real-Time Supplements - Center Level Metric

Table 3.1 CBER - PMA Real-Time Supplements MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
Supplements Received	3	1			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	3	0			
MDUFA IV Decision Goal Met	3	0			
Supplements Pending MDUFA IV Decision	0	1			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	N/A			

Table 3.2 CBER - PMA Real-Time Supplements Performance Metric - Rate of Not Approvable

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	3	1			
Number With MDUFA IV Decision	3	0			
Number of Not Approvable	0	0			
Rate of Not Approvable	0%	N/A			

Table 3.3 CBER - PMA Real-Time Supplements Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00			
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00			

## Section 6 510(k) Center Level Metrics (Excludes Third Party Review)

Table 6.1 CBER - 510(k) Acceptance Review Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	53	30			
Closed Before RTA Action	0	0			
Number Accepted	40	21			
Number Without a RTA Review and > 15 Days Since Date Received	2	0			
Number Without a RTA Review and <= 15 Days Since Date Received	0	5			
Number Not Accepted	11	4			
Rate of Submissions Not Accepted for Review	20.75%	16.00%			

Table 6.2 CBER - 510(k) Substantive Interaction Performance Goal

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days
Eligible for SI	49	23			
Deleted or Withdrawn Prior to SI	0	0			
SI Within 60 FDA Days	49	19			
SI Over 60 FDA Days	0	0			
SI Pending Within 60 FDA Days	0	4			
SI Pending Over 60 FDA Days	0	0			
510(k)s NSE Without SI	0	0			
Current SI Performance Percent Within 60 FDA Days	100%	100%			

**Table 6.3 CBER - 510(k) Substantive Interaction Metric - Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number of Substantive Interaction	49	19			
Average Number of FDA Days to Substantive Interaction	50.60	37.37			
20th Percentile FDA Days to Substantive Interaction	43	17			
40th Percentile FDA Days to Substantive Interaction	57	21			
60th Percentile FDA Days to Substantive Interaction	59	53			
80th Percentile FDA Days to Substantive Interaction	60	59			
Maximum FDA Days to Substantive Interaction	60	60			

**Table 6.4 CBER - 510(k) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>
510(k)s Accepted	49	23			
Non-MDUFA IV Decision	5	0			
MDUFA IV Decision (SE/NSE)	42	10			
MDUFA IV Decision Within 90 FDA Days	42	10			
510(k)s Pending MDUFA IV Decision	2	13			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	100%	100%			

**Table 6.5 CBER - 510(k) Time to MDUFA IV Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Average Review Cycles	1.29	1.15			
Number With MDUFA IV Decision	42	10			
<b>Average Number of FDA Days to MDUFA IV Decision</b>	75.26	49.70			
20th Percentile FDA Days to MDUFA IV Decision	65	18			
40th Percentile FDA Days to MDUFA IV Decision	85	28			
60th Percentile FDA Days to MDUFA IV Decision	88	59			
80th Percentile FDA Days to MDUFA IV Decision	90	78			
Maximum FDA Days to MDUFA IV Decision	90	85			
<b>Average Number of Industry Days to MDUFA IV Decision</b>	22.78	15.80			
20th Percentile Industry Days to MDUFA IV Decision	0.00	0.00			
40th Percentile Industry Days to MDUFA IV Decision	0.00	0.00			
60th Percentile Industry Days to MDUFA IV Decision	0.00	0.00			
80th Percentile Industry Days to MDUFA IV Decision	57.00	0.00			
Maximum Industry Days to MDUFA IV Decision	178.00	80.00			
<b>Average Number of Total Days to MDUFA IV Decision</b>	98.05	65.50			
20th Percentile Total Days to MDUFA IV Decision	76	26			
40th Percentile Total Days to MDUFA IV Decision	86	30			
60th Percentile Total Days to MDUFA IV Decision	90	77			
80th Percentile Total Days to MDUFA IV Decision	126	85			
Maximum Total Days to MDUFA IV Decision	268	161			

**Table 6.6 CBER - 510(k) Performance Metric - Rates of SE, NSE, Withdrawal, and Delete Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
510(k) Accepted	49	23			
Number With MDUFA IV Decision	42	10			
Number of SE Decision	42	10			
Number of NSE Decision	0	0			
Number of Withdrawal	2	0			
Number of Deleted	2	0			
Rate of SE Decision	100%	100%			
Rate of NSE Decision	0%	0%			
Rate of Withdrawal	4%	0%			
Rate of Deleted	4%	0%			

**Table 6.7 CBER - 510(k) Performance Metric - Submissions Missing Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 6.8 CBER - LDT 510(k) MDUFA IV Decision Metric**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	0	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision (SE/NSE)	0	0			
MDUFA IV Decision Within 90 FDA Days	0	0			
510(k)s Pending MDUFA IV Decision	0	0			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	N/A	N/A			

**Table 6.9 CBER - Conventional IVD (Non-LDT) 510(k) MDUFA IV Decision Metric**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	14	6			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision (SE/NSE)	14	2			
MDUFA IV Decision Within 90 FDA Days	14	2			
510(k)s Pending MDUFA IV Decision	0	4			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	100.00%	100.00%			

## Section 8 De Novo Center Level Metrics

**Table 8.1 CBER - De Novo Acceptance Review Decision\***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	0	1			
Closed Before RTA Action	N/A	N/A			
Number Accepted First RTA Cycle	N/A	N/A			
Number Without a RTA Review and > 15 Days Since Date Received	N/A	N/A			
Number Without a RTA Review and <= 15 Days Since Date Received	N/A	N/A			
Number Not Accepted	N/A	N/A			
Rate of Submissions Not Accepted for Review	N/A	N/A			

\* RTA was implemented on TBD, thus RTA metrics in table 8.1 include only De Novos received on or after TBD. All other tables include De Novos received on or after October 1, 2017.

**Table 8.2 CBER - De Novo MDUFA IV Decision Performance Goals**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	50% Within 150 FDA Days	55% Within 150 FDA Days	60% Within 150 FDA Days	65% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	0	1			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	0	0			
MDUFA IV Decisions Within 150 FDA Days	0	0			
De Novos Pending MDUFA IV Decision	0	1			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	N/A	N/A			

**Table 8.3 CBER - De Novo Time to MDUFA IV Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Average Review Cycles	0.00	0.00			
Number With MDUFA IV Decision	0	0			
<b>Average FDA Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile FDA Days to MDUFA IV Decision	0	0			
40th Percentile FDA Days to MDUFA IV Decision	0	0			
60th Percentile FDA Days to MDUFA IV Decision	0	0			
80th Percentile FDA Days to MDUFA IV Decision	0	0			
Maximum FDA Days to MDUFA IV Decision	0	0			
<b>Average Industry Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	0	0			
80th Percentile Industry Days to MDUFA IV Decision	0	0			
Maximum Industry Days to MDUFA IV Decision	0	0			
<b>Average Total Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile Total Days to MDUFA IV Decision	0	0			
40th Percentile Total Days to MDUFA IV Decision	0	0			
80th Percentile Total Days to MDUFA IV Decision	0	0			
Maximum Total Days to MDUFA IV Decision	0	0			



**Table 8.4 CBER - De Novo Performance Metrics - Rate of Grant, Decline, Withdrawal and Delete Decisions**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0	1			
Number With MDUFA IV Decisions	0	0			
Number With Granted Decisions	0	0			
Number With Declined Decisions	0	0			
Number of Withdrawals	0	0			
Number Deleted	0	0			
Rate of Granted Decisions	N/A	N/A			
Rate of Declined Decisions	N/A	N/A			
Rate of Withdrawals	N/A	N/A			
Rate of Deleted	N/A	N/A			

**Table 8.5 CBER - De Novo Performance Metrics-Submissions Missing Performance Goals**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00			
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00			

**Table 8.6 CBER - LDT De Novo MDUFA IV Decision Metrics**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0	0			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	0	0			
MDUFA IV Decisions Within 150 FDA Days	0	0			
De Novos Pending MDUFA IV Decision	0	0			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	N/A	N/A			

**Table 8.7 CBER - Conventional IVD (non-LDT) De Novo MDUFA IV Decision Metrics**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0	1			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	0	0			
MDUFA IV Decisions Within 150 FDA Days	0	0			
De Novos Pending MDUFA IV Decision	0	1			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	N/A	N/A			

## Section 9 Pre-Sub Center Level Metrics

**Table 9.1 CBER - Pre-Sub Acceptance Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	76	35			
Closed Before RTA Action	5	1			
Number Accepted First RTA Cycle	69	30			
Number Without a RTA Review and > 15 Days Since Date Received	1	0			
Number Without a RTA Review and <= 15 Days Since Date Received	0	3			
Number Not Accepted	1	1			
Rate of Submissions Not Accepted for Review	1.41%	3.23%			

**Table 9.2 CBER - MDUFA IV Pre-Sub Performance Goals**

Performance Metric	MDUFA IV Goal (# of Submissions Received During FY with Written Feedback Provided by Day 70 or 5 Days Prior to Meeting)				
	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	≥ 1530 Submissions	≥ 1645 Submissions	≥ 1765 Submissions	≥ 1880 Submissions	≥ 1950 Submissions
Written Feedback Sent	70	19			
Written Feedback Provided Within MDUFA IV Goal	70	19			

**Table 9.3 CBER - Pre-Sub Time to MDUFA IV Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	70	19			
Average FDA Days to Written Feedback	57.86	61.21			
20th Percentile FDA Days to Written Feedback	47	56			
40th Percentile FDA Days to Written Feedback	58	60			
60th Percentile FDA Days to Written Feedback	64	63			
80th Percentile FDA Days to Written Feedback	67	68			
Maximum FDA Days to Written Feedback	72	70			

**Table 9.4 CBER - MDUFA IV Pre-Sub Performance Metrics - Meeting Scheduling**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meetings Not Scheduled By Day 30	0	0			
Average Days to Scheduling for Meetings Scheduled After Day 30	0.00	0.00			

**Table 9.5 CBER - MDUFA IV Pre-Sub Performance Metrics - Meeting Minutes**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meeting Held	42	7			
Meeting Minutes Submitted Within 15 Days of Meeting	33	7			
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0			
Meeting Minutes Past 15 Days of Meeting	9	0			
Meeting Minutes Not Submitted and >15 Days Since Meeting	0	0			
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	78.57%	100.00%			

## Section 10 IDE- Center Level Metric

Table 10.1 CBER - IDE MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of IDEs Received	15	8			
Average Number of Cycles to IDE Approval or Conditional Approval	1.10	1.00			
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.10	0.00			

**BLA**

**CBER – Annual General Metric Report for BLAs**

**\*\*Annual Metrics and Goals will be reported in the Annual Report\*\***

**BLA Efficacy Supplements**

**CBER – Annual General Metric Report for BLA Efficacy Supplements**

**\*\*Annual Metrics and Goals will be reported in the Annual Report\*\***

**BLA Prior Approval Manufacturing Supplements**

**CBER – Annual General Metric Report for BLA PAS Supplements**

**\*\*Annual Metrics and Goals will be reported in the Annual Report\*\***

**BLA/BLA Resubmissions**

**CBER – Annual General Metric Report for BLA/BLA Resubmissions**

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**FY 2019 Medical Device User Fee Collections  
as of March 31th, 2019  
Excludes Unearned Fees**

	<b>Receipts</b>	<b>Refunds</b>	<b>Net</b>	<b>Authorized</b>	<b>% of Authorized</b>
Registration Fees	\$127,795,884	\$29,044	\$127,766,840		
Application Fees	\$30,662,907	\$249,631	\$30,413,276		
<b>Total</b>	<b>\$158,458,791</b>	<b>\$278,675</b>	<b>\$158,180,116</b>	<b>\$204,730,000</b>	<b>77%</b>

**Medical Device User Fee Collection History  
Excludes Unearned Fees, Includes Refunds**

	<b>FY 2003</b>	<b>FY 2004</b>	<b>FY 2005</b>	<b>FY 2006</b>	<b>FY 2007</b>
MD I	\$21,620,549	\$26,281,779	\$31,728,269	\$34,417,751	\$28,031,569
	<b>FY 2008</b>	<b>FY 2009</b>	<b>FY 2010</b>	<b>FY 2011</b>	<b>FY 2012</b>
MD II	\$47,706,236	\$57,554,216	\$63,932,631	\$70,139,400	\$65,811,376
	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
MD III	\$101,249,618	\$121,120,517	\$134,499,834	\$146,280,182	\$136,969,284
	<b>FY 2018</b>	<b>FY 2019</b>			
MD IV	\$189,601,746	\$158,180,116			

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**MDUFA IV Commitment Letter - VI. Performance Reports**  
**2.12. Number of discretionary fee waivers or reductions granted by type of submission<sup>1/</sup>**

<b>CDRH Data 2nd Quarter FY2019 by Submission type</b>	<b># Waived</b>	<b># Reduced</b>
<b>Full Fee applications<sup>2/</sup></b>		
PMA	1	4
PDP	0	0
PMR	0	0
BLA		
BLA efficacy supplement		
<b>Panel Track Supplements</b>	<b>2</b>	<b>3</b>
<b>De Novo Classification</b>	<b>6</b>	<b>21</b>
<b>180-Day Supplements</b>	<b>0</b>	<b>9</b>
<b>Real-Time Supplements</b>	<b>0</b>	<b>16</b>
<b>510(k)s</b>	<b>24</b>	<b>653</b>
<b>30-day Notices</b>	<b>2</b>	<b>45</b>
<b>513(g)s</b>	<b>0</b>	<b>16</b>
<b>PMA Annual Report</b>	<b>0</b>	<b>23</b>
<b>Total</b>	<b>35</b>	<b>790</b>

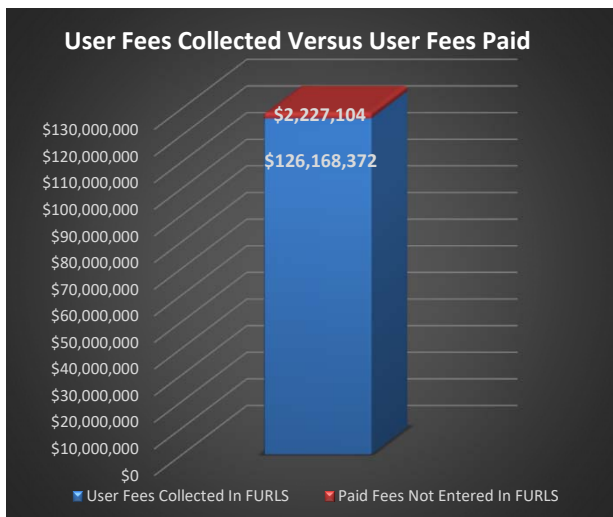
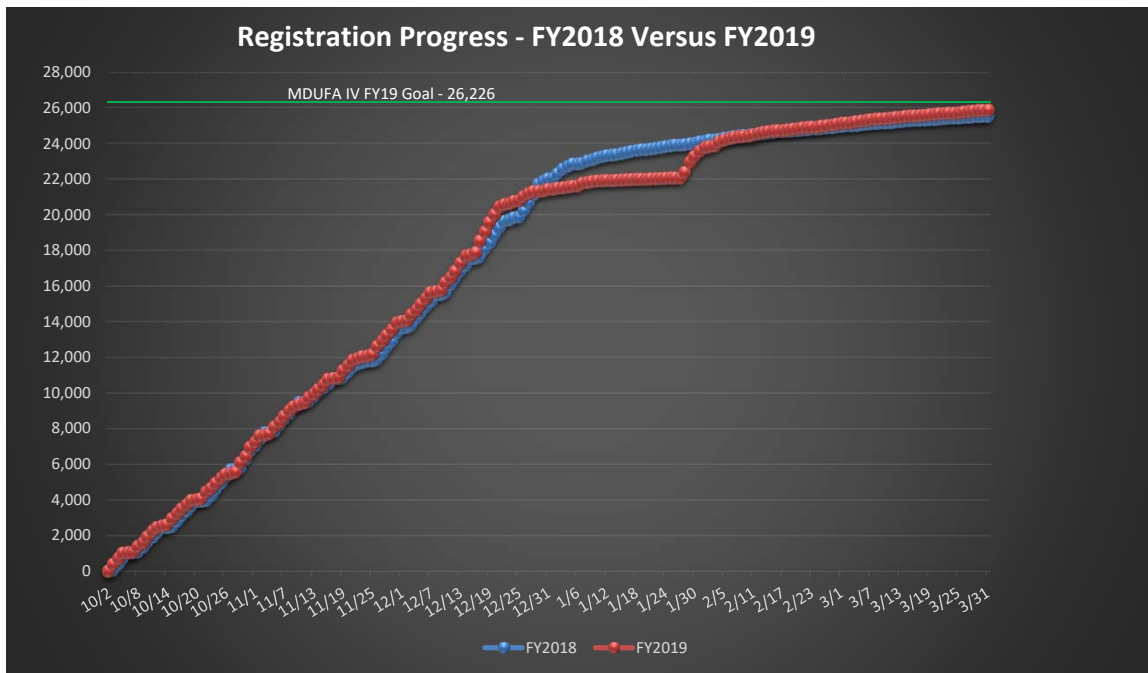
<sup>1/</sup> User fees may be waived for several reasons, including but not limited to: the submitter is a State or Federal Government entity who does not intend to distribute the device commercially; the proposed conditions of use for the device involved are solely for a pediatric population; and, the submitter is a small business submitting their first premarket approval application or premarket report. User fees are reduced for small businesses. 510(k)s reviewed through the Third Party Review program are not included because FDA does not collect user fees for 510(k)s reviewed through that program. Counts are cumulative for the Fiscal Year.

<sup>2/</sup> As specified in the MDUFA 4 Commitment Letter, BLAs, BLA efficacy supplements, and other CBER data will be reported annually.

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# MDUFA IV Registrations - Second Quarter Summary FY2019

Current Active Registrations by Type	FY19 Q2			FY18 Year End Active Totals			FY19 vs End FY18
	Domestic	Foreign	Total	Domestic	Foreign	Total	
Manufacturer/ Complaint File Handler	6,022	9,565	15,587	6,199	9,926	16,125	96.66%
Contract Manufacturer	1,068	1,487	2,555	1,113	1,481	2,594	98.50%
Contract Sterilizer	72	135	207	73	140	213	97.18%
Specification Developer	1,619	495	2,114	1,708	502	2,210	95.66%
Reprocessor of Single Use Devices	26	2	28	25	3	28	100.00%
U.S. Manufacturer of Export Only Devices	128	0	128	137		137	93.43%
Repackager/Relabeler	1,049	176	1,225	1,144	185	1,329	92.17%
Remanufacturer	18	9	27	22	13	35	77.14%
Foreign Exporter/Private Label Distributor		919	918		976	976	94.06%
Initial Importer	2,960		2,960	3,264		3,264	90.69%
Unknown	2	3	5	17	13	30	16.67%
<b>Total:</b>	<b>12,964</b>	<b>12,791</b>	<b>25,755</b>	<b>13,702</b>	<b>13,239</b>	<b>26,941</b>	<b>95.60%</b>



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# **Center for Devices and Radiological Health Internal Training Summary Report**

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**Q2 FY19**

October 2018 – March 2019

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Prepared by: The Division of Employee Training and Development (DETD)

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As of: 4/24/2019

The FDA continues to invest in internal and external training opportunities supporting medical device regulation. The Division of Employee Training and Development (DETD) is CDRH's internal resource for scientific, regulatory, leadership training, career development programs, and customized learning opportunities. We help further the Center's mission by championing employee growth across the Center's eight offices. Our approach to improving performance combines classroom, experiential, and online learning with mentoring, self-study initiatives, and specialty programs. We are committed to providing CDRH employees with the knowledge and skills needed to maximize their organizational and individual potential.

Table X provides a summary of internal training conducted in CDRH between October 1, 2018 and March 31, 2019. DETD offered 297 learning events addressing reviewer training, new scientific technologies, law, regulation and guidance updates, and leadership and professional development. The training was designed to support the Medical Device User Fee Amendment (MDUFA) goals and program activities.



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**Table X – FY19 CDRH Internal Training Conducted by DETD:***October 1, 2018 and March 31, 2019*

Category	Program	# of Learning Events	Total # of Completions	Total Training Hours
<b>Regulatory and Law (LAW) Training</b>	MDUFA IV	5	259	213
	ELP	4	35	560
	Other LAW	184	4348	4565
<i>LAW Subtotal:</i>		<i>193</i>	<i>4642</i>	<i>5338</i>
<b>Leadership Development Training (LED)</b>	LEAD: Leadership for Managers	24	246	494
	Leadership for Non-Managers	2	32	160
	Other LED	13	222	1487
<i>LED Subtotal:</i>		<i>39</i>	<i>500</i>	<i>2141</i>
<b>Professional Development (PRO) Training</b>	New Employee Orientation (NEO)	1	15	105
	Other PRO	21	306	2384
<i>PRO Subtotal:</i>		<i>22</i>	<i>321</i>	<i>2489</i>
<b>Center-Specific Information Technology (CIT) Training</b>	Premarket IT	6	140	142
	Other CIT	4	19	10
<i>CIT Subtotal:</i>		<i>10</i>	<i>159</i>	<i>152</i>
<b>Science (SCI) Training</b>	All SCI	33	674	1351
<i>SCI Subtotal:</i>		<i>33</i>	<i>674</i>	<i>1351</i>
<b>Grand Total:</b>		<b>297</b>	<b>6296</b>	<b>11471</b>

## CDRH Informal Training

### CDRH Informal Training:

DETD implemented a process for tracking Informal training in 2015. Unlike Formal Center-wide training managed by DETD, Informal training targets specific audiences and addresses specialized training topics. Informal training is offered at the Office, Division and Branch levels and is conducted as on-the-job training, All-Hands meetings, small group sessions and classroom and remote training. Formal and informal training is necessary to meet the mission-critical training needs of Center staff. Examples of informal training content include:

- Additional instruction provided following Formal training (e.g. Medical Device Regulation training)
- Policy change updates (e.g. Technology, MDUFA, new guidance)
- Best practices used in a specific product area

### CDRH Informal Training: *October 1, 2018 and March 31, 2019*

Year	# of Learning Events	Total # of Participants	Total Contact Hours
FY'15	34	1249	3350
FY'16	42	978	2122
FY'17	113	2845	8956
FY'18	61	1692	5650
FY'19	21	417	555
<b>Total:</b>	<b>271</b>	<b>7181</b>	<b>20633</b>

## Premarket Reviewer Training - RCP

### Reviewer Certification Program (RCP):

The RCP curriculum is a 30.5-hour program consisting of online and classroom courses essential to new reviewers during their first 60 days of hire. The condensed course design results in reviewers receiving the most salient knowledge in a timely fashion. After completion of the RCP, reviewers enroll in advanced courses designed to further enhance their knowledge and skills. The curriculum consists of the following components:

- 11 classroom courses, including a program Orientation and Capstone, totaling 15.5 hours of training
- 11 online courses, totaling 15.0 hours
- 7 Advanced courses, to be taken within a year of employment
- Practical activities and hands-on exercises
- Knowledge assessments

### RCP Training by Cohort: *October 1, 2018 and March 31, 2019*

Cohort	# of Classroom Learning Events	# of Online Learning Events	Office	# of Participants	# of Completions	# of Training Hours
<b>Fall 1 2018 Cohort</b>	11	11	OC	2	20	26
			OCD	1	12	15
			ODE	5	53	66
			OIR	10	164	202
			OSEL	4	72	88
			<b>Subtotal:</b>	<b>22</b>	<b>321</b>	<b>397</b>
<b>Fall 2 2018 Cohort</b>	11	11	OC	1	5	7
			OCD	2	11	15
			ODE	6	45	52
			OIR	2	30	33
			OSEL	8	59	69
			<b>Subtotal:</b>	<b>19</b>	<b>150</b>	<b>176</b>
<b>Spring 1 2019 Cohort</b>	11	11	OC	2	19	27
			ODE	3	65	83
			OIR	2	38	45
			OSEL	5	106	122
			<b>Subtotal:</b>	<b>12</b>	<b>228</b>	<b>277</b>
<b>Total:</b>	<b>33</b>	<b>33</b>	<b>-</b>	<b>53</b>	<b>699</b>	<b>850</b>

## Premarket Reviewer Training - ELP

### **Experiential Learning Program (ELP):**

The Experiential Learning Program (ELP) is a collaborative approach to closing the knowledge gap between emerging and innovative technology and the review of resulting medical devices. The Program fosters an understanding of how medical devices are developed, clinically tested, manufactured, and utilized. Staff involved in medical device regulation visit ELP sites identified by training need and selected through a formalized proposal submission process.

### **ELP Training Completed:** *October 1, 2018 and March 31, 2019*

# of Site Visits	# of Attendees	Total Training Hours	Focus Areas
4	35	560	• Innovation

### **ELP Training Completed by Office:** *October 1, 2018 and March 31, 2019*

Office	Total # of Attendees	Total Training Hours
<b>OC</b>	6	88
<b>OCD</b>	2	32
<b>ODE</b>	24	408
<b>OIR</b>	1	8
<b>OSB</b>	2	24
<b>Total:</b>	<b>35</b>	<b>560</b>

## Leadership Training - LEAD

### Leadership Enhancement and Development (LEAD) Program:

The LEAD Program is a mandatory Supervisory Training Program targeting CDRH Supervisors, Managers, and Non-Bargaining Unit Team Leaders. The LEAD curriculum supports the CDRH Management Competencies and addresses the supervisory training requirements as mandated in 5 CFR 412.

### LEAD Training Completed: *October 1, 2018 and March 31, 2019*

Category	# of Learning Events	Total # of Completions	Total Training Hours	Examples of Training Conducted
<b>LEAD</b>	24	246	494	<ul style="list-style-type: none"> <li>• Diversity, Unconscious Bias</li> <li>• Effective Performance Management</li> <li>• CDRH Manager Orientation Program</li> <li>• Leading Through Change</li> <li>• Leading with Personal Integrity and Ethics</li> <li>• Managing Up, Communicating with your Boss</li> <li>• CDRH Ethics Refresher Series: What is an Outside Activity?</li> </ul>

### LEAD Training Completed by ODE and OIR: *October 1, 2018 and March 31, 2019*

Office	Total # of Managers/Supervisors*	# of Training Participants	Training Hours Required**	% of Required Training Hours Completed
ODE	73	60	1168	33%
OIR	40	35	640	11%
<b>Total:</b>	<b>113</b>	<b>95</b>	<b>1808</b>	<b>22%</b>

\*The number of supervisors may vary by quarter based on data provided from each Office.

\*\*This data is based on the 16-hour minimum annual training requirement for managers with 3 or more years of experience. New supervisors within the federal government have an additional 24-hour training requirement, for a total of 40 hours.

## Leadership Training - LRP

### Leadership Readiness Program (LRP):

The Leadership Readiness Program (LRP) is a one-year learning opportunity for employees considering a supervisory career path. The LRP facilitates learning in the areas of mentoring, self-study, classroom-based courses, and other practical activities. The target audience is highly motivated, non-managers at the GS 12, 13, and non-supervisory 14 levels or equivalent Commissioned Corps Officers rank, with a minimum of two years of FDA experience. Participants are selected for the one-year program through a competitive process. They remain in their current position and participate in the LRP as a collateral activity.

### LRP Participant Data:

LRP Program Year	Office	# of Enrolled Participants	# of Participant Completions
<b>2006 - 2007</b>	OIVD	3	3
	ODE	13	12
<b>2008 - 2009</b>	OIVD	3	3
	ODE	10	10
	Other	17	16
<b>2010 - 2011</b>	OIVD	3	3
	ODE	9	8
	Other	8	8
<b>2012 - 2013</b>	OIR	3	3
	ODE	6	6
	Other	11	11
<b>2014 - 2015</b>	OIR	2	2
	ODE	6	6
	Other	12	12
<b>2016-2017</b>	OIR	3	3
	ODE	9	9
	Other	8	8
<b>2018-2019</b>	OIR	4	-
	ODE	11	-
	Other	7	-
<b>Total:</b>		<b>148</b>	<b>123</b>

## CDRH Training Courses by Category:

The following section contains a sampling of DETD courses provided during FY19.

### Regulatory and Law (LAW) Training:

Benefit-Risk Guidance – Online	This online course outlines the factors to consider when making benefit-risk determinations for Premarket Approval (PMA) applications and De novo petitions.
Master Four-Part Harmony	This course provides instruction on writing deficiencies that are clear, concise, and in the appropriate format.
Master Technical Writing	This course teaches the basic elements of plain language writing and how to use them to write clear and succinct technical documents.
Pre-Submission Program, Meetings with FDA, IDEs, and Clinical Trials	This course provides practical knowledge about the reviewer’s roles and responsibilities related to the Pre-submission program, meetings and clinical trials.
Effective Communication Skills for Technical and Scientific Professionals	This course addresses real-world communication strategies for scientific and technical professionals.
Introduction to Premarket Review	This course describes the essential elements in premarket review.
Premarket programs: 510k and 513g	This course provides an understanding of the device classifications.
Conducting 510k Reviews	This course provides an overview of the 510(k) flowchart.
Basics of Writing Consult Requests and Reviews	This course provides examples of the essential elements of a written pre-market consulting review.
Premarket Programs: IDEs	This course provides an understanding of the regulatory submission that permits clinical investigation of medical devices.
Premarket Programs: PMA and HDE	This training outlines the types of PMA submissions and the information necessary to determine when a PMA is required.
Premarket Review Clinic	The training prepares the participant to complete the CAPSTONE assignments distributed following completion of the Reviewer Certification Program.
Reviewer Certification CAPSTONE	This training includes interactive sessions that discuss the varying types and requirements of medical device applications.
Regulatory Basics (online)	This training describes the source and effect of law, regulation, and guidance on the work conducted within CDRH.
MDUFA IV Overview	This training provides an overview of the Medical Device User Fee Act of 2017.



Basics of 4-Part Harmony in Lead and Consult Reviews	This training provides participants with instruction on the elements needed to write clear and concise deficiencies.
RCP: Standards Overview	This training provides an overview of Standards and how they are applied.
RCP: Standards Resources and Premarket Use	This training provides participants with instruction on how to find recognized Standards and discusses how Standards are used in premarket submissions.
RCP: Basics of Standards in Premarket Review	This training provides participants with instruction on locating recognized Standards, Standard's guidance, and accessing Standard's library resources.
Overview of FOIA	This training provides an overview of FOIA applications and discusses the impact of OPEN Government amendments to FOIA.
SMART Template	This class provides instruction for using a programmed Microsoft Word document to create review documents.
RCP Premarket Program: De Novo Classification	This class describes the legal basis for the De Novo pathway.

### **Leadership Development Training for Managers and Non-Managers (LED) Training:**

Handling People with Diplomacy & Tact	This course provides participants with a big-picture mentality regarding their work and a blueprint for productivity. Participants also learn techniques for empowering their team and holding each team member accountable.
LEAD: CDRH Manager Orientation Program	This training provides managers with resources to navigate professional development and human resource information for themselves as well as the employees they supervise.
LEAD: Diversity, Unconscious Bias	This course provides organizations with an understanding of unconscious bias, the tools to confront and combat its negative effects; and the ability to recognize when the impact on decision making.
LEAD: Managing Up, Communicating with Your Boss	This course focuses on the skills necessary for managing upward including effective communication, achieving goals and providing constructive feedback.
Negotiating with Confidence	This interactive program enables participants to better communicate their needs and negotiate with confidence using practical application.
Critical Thinking and Problem Solving	This two-day workshop is designed to provide an understanding of the differences between critical thinking styles and how they are applied in the everyday world.

### Professional Development (PRO) Training:

Growing Creativity and Innovation	This course explores both the nature and nurture of creativity and innovation and the capacity for putting these vital skills into everyday practice.
Strategic Planning and Analytical Thinking	This course provides participants with an understanding of the different analytical styles and how they affect and inhibit analytical thinking. Tools used in analytical thinking and ways to increase creative thinking are also addressed.
Critical TOP Thinking	This training provides an overview and tools for Thought Optimized Processing (TOP) Thinking. Participants learn how to accomplish TOP in a pragmatic way while maintaining precision and accuracy. Instruction also addresses the ability to think creatively and critically while ensuring that reasoning is objective.
Influencing Others for High Impact	This seminar focuses on the skills and strategies necessary to increase the likelihood that others will say "yes". The course instruction includes an opportunity to translate theory into practice.

### Science (SCI) Training:

Introduction to Public Health	This course provides the framework for understanding public health concepts, the fundamentals of epidemiology, medical product surveillance systems, and the public health determinants that influence medical device development.
CDRH Laboratory Waste Management – online	This course gives an overview of the requirements for waste handling in CDRH laboratories, as well as a brief description of the laboratory Emergency Procedures.
Regenerative Medicine Series	The Regenerative Medicine Seminar Series offers a variety of seminars that examine the restoration and function of the human form within the context of translational research involving medical devices and biologics.
Reprocessing Medical Devices in Health Care Settings	This course is designed to provide staff involved in medical device regulation with the knowledge necessary to perform routine labeling evaluations based on FDA's 2015 Guidance, "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling."

### Center-Specific IT (CIT) Training

Using IT Systems in Premarket Review	This online course is designed to provide an overview of the IT systems used in medical device regulation.
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