PMA Monthly approvals from 6/1/2020 to 6/30/2020

Original

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P190021	06/16/2020	PMAO - PMA Origi	REACTIV8 IMPLANTABLE NEUROSTIMULATION SYSTEM	MAINSTAY MEDICAL LIMITED	Approval for the ReActiv8 System is indicated for bilateral stimulation of the L2 medial branch of the dorsal ramus as it crosses the transverse process at L3 as an aid in the management of intractable chronic low back pain associated with multifidus muscle dysfunction, as evidenced by imaging or physiological testing in adults who have failed therapy including pain medications and physical therapy and are not candidates for spine surgery.
P200014	06/18/2020	PMAO - PMA Origi	COBAS® EZH2 MUTATION TEST	ROCHE MOLECULAR SYSTEM, INC.	Approval for The cobas® EZH2 Mutation Test. The device is a real-time allele-specific PCR test for qualitative detection of single nucleotide mutations for Y646N, Y646F or Y646X (Y646H, Y646S, or Y646C), A682G, and A692V of the EZH2 gene in DNA extracted from formalin fixed paraffin embedded (FFPE) human follicular lymphoma tumor tissue specimens. The cobas® EZH2 Mutation Test is intended for the identification of follicular lymphoma patients with an EZH2 mutation for treatment with TAZVERIK (tazemetostat), in accordance with the approved therapeutic product labeling.

Total: 2

Supplements

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N970003/S251	06/15/2020	R - Real-Time Proc	PULSAR/PULSAR MAX IMPLANTABLE PULSE GENERATOR SYSTEM WITH CONSULT SOFTWARE	BOSTON SCIENTIFIC CORP.	Approval for Model 3892 Altrua/Insignia/Nexus I Software Support Application v 1.04, Model 3909 Multiple Application Utility v 1.09, Model 3920 Platform Operating System v1.08, Model 3923 Quick Start Application v1.05 software applications of the Model 3300 LATTITUDE Programming System.
P830061/S181	06/02/2020	R - Real-Time Proc	STEROID TIP(TM) MODEL 4503&4003 TRANSVENOUS PACING	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for a change to the lead serial number ink/foil material for select implantable leads.
P840001/S450	06/25/2020	N - Normal 180 Day	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Approval for the new WR9200 Wireless Recharger Subsystem and associated labeling. The new WR9200 Wireless Recharger Subsystem is intended to recharge the Activa RC implantable neurostimulator (INS) for Deep Brain Stimulation Therapy and the following Restore INSs for Spinal Cord Stimulation Therapy: RestoreUltra; RestoreUltra SureScan MRI; RestoreSensor; and RestoreSensor SureScan MRI.

Data as of 07/08/2020 03:47 AM

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P850089/S147	06/02/2020	R - Real-Time Proc	CAPSURE SP, CAPSURE, CAPSURE 2 LEADS, EXCELLENCE S, IMPULSE, IMPLUSE II EXCELLENCE SS, LEADS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Approval for a change to the lead serial number ink/foil material for select implantable leads.
P860057/S197	06/23/2020	O - Normal 180 Day	EDWARDS LIFESCIENCES PERIMOUNT AORTIC AND MITRAL BIOPROSTHESES	EDWARDS LIFESCIENCE S, LLC.	Approval for a labeling change for the Carpentier-Edwards PERIMOUNT® Magna Ease® Aortic Heart Valve, model 3300TFX, to update the Instructions for Use (IFU) reflecting data from the completed Post-Approval Study.
P880086/S308	06/30/2020	N - Normal 180 Day	ACCENT, IDENTITY, VERITY, VICTORY AND ZEPHYR PACEMAKERS	ST. JUDE MEDICAL, INC.	Approval for Avant, Neutrino NxT, Gallant, and Entrant families of ICDs and CRT-Ds; myMerlinPulse mobile application; Merlin PCS 3650 Programmer Software Model 3330 v25.0.1; and Merlin.net MN5000 v7.8.
P890003/S429	06/02/2020	R - Real-Time Proc	SYNERGYST II PULSE GENERATOR MODELS 7070 & 7071	MEDTRONIC, INC.	Approval for a change to the lead serial number ink/foil material for select implantable leads.
P900061/S158	06/02/2020	R - Real-Time Proc	MEDTRONIC PCD TACHYARRHYTHMIA CONTROL SYSTEM	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Approval for a change to the lead serial number ink/foil material for select implantable leads.
P910023/S423	06/30/2020	N - Normal 180 Day	CADENCE(R) TIERED THERAPY DEFIBRILLATION SYSTEM	ST. JUDE MEDICAL	Approval for Avant, Neutrino NxT, Gallant, and Entrant families of ICDs and CRT-Ds; myMerlinPulse mobile application; Merlin PCS 3650 Programmer Software Model 3330 v25.0.1; and Merlin.net MN5000 v7.8.
P910077/S177	06/15/2020	R - Real-Time Proc	VENTAK(R) PRX (TM) MODEL 1700,1705 PULSE GENERATOR	BOSTON SCIENTIFIC	Approval for Model 3892 Altrua/Insignia/Nexus I Software Support Application v 1.04, Model 3909 Multiple Application Utility v 1.09, Model 3920 Platform Operating System v1.08, Model 3923 Quick Start Application v1.05 software applications of the Model 3300 LATTITUDE Programming System.
P920015/S243	06/02/2020	R - Real-Time Proc	MEDTRONIC(R) TRANSVENE LEAD SYSTEM	MEDTRONIC INC.	Approval for a change to the lead serial number ink/foil material for select implantable leads.
P920047/S123	06/04/2020	R - Real-Time Proc	EPT-1000 CARDIAC ABLATION SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for a design change to the Control Wire Sleeve of the Blazer Prime HTD and Blazer Prime XP cardiac ablation catheters.
P930039/S211	06/02/2020	R - Real-Time Proc	MEDTRONIC(R) CAPSUREFIX LEAD MODEL 4068,4067,4568	MEDTRONIC, INC.	Approval for a change to the lead serial number ink/foil material for select implantable leads.
P950022/S132	06/04/2020	O - Normal 180 Day	TVL(TM) LEAD SYSTEM	ST. JUDE MEDICAL, INC.	Approval to include long-term safety and effectiveness data from the Cardiac Lead Assessment Study in the device labeling.
P950024/S092	06/02/2020	R - Real-Time Proc	MEDTRONIC(R) CAPSURE (R) EPI PACING LEAD MODEL 4695	MEDTRONIC INC.	Approval for a change to the lead serial number ink/foil material for select implantable leads.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P960009/S361	06/24/2020	N - Normal 180 Day	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Approval for the following: 1) Model B35200 Percept PC Implantable Neurostimulator (INS); 2) Model B31060 Connector Plug; 3) Updates to the Model A610 Clinician Programmer Application (PPA) Software to version 2.0; 4) Updates to the Model A620 Patient Programmer Application (CPA) to version 2.0; 5) Updates to the Model 8880T2 Communicator (clinician telemetry device) firmware; 6) New Model TH91 Handset and Communicator kit; and 7) Labeling changes in physician and patient labeling for existing products, to be consistent with the proposed labeling for the new Percept PC System.
P960009/S365	06/25/2020	N - Normal 180 Day	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Approval for the new WR9200 Wireless Recharger Subsystem and associated labeling. The new WR9200 Wireless Recharger Subsystem is intended to recharge the Activa RC implantable neurostimulator (INS) for Deep Brain Stimulation Therapy and the following Restore INSs for Spinal Cord Stimulation Therapy: RestoreUltra; RestoreUltra SureScan MRI; RestoreSensor; and RestoreSensor SureScan MRI.
P960040/S450	06/15/2020	R - Real-Time Proc	VENTAK AV AICD VENTAK PRIZM DR/VR, VITALITY, COFIENT, AND TELIGEN AUTOMATIC IMPLANTABLE CARDIOVETER DEFIBRILLATOR SYSTEM	BOSTON SCIENTIFIC	Approval for Model 3892 Altrua/Insignia/Nexus I Software Support Application v 1.04, Model 3909 Multiple Application Utility v 1.09, Model 3920 Platform Operating System v1.08, Model 3923 Quick Start Application v1.05 software applications of the Model 3300 LATTITUDE Programming System.
P970013/S082	06/30/2020	N - Normal 180 Day	MICRONY PACEMAKERS	ST. JUDE MEDICAL, INC.	Approval for Avant, Neutrino NxT, Gallant, and Entrant families of ICDs and CRT-Ds; myMerlinPulse mobile application; Merlin PCS 3650 Programmer Software Model 3330 v25.0.1; and Merlin.net MN5000 v7.8.
P980007/S041	06/05/2020	N - Normal 180 Day	AXSYM FREE PSA	ABBOTT LABORATORIES	Approval for the migration of the Abbott ARCHITECT Free PSA assay to the Alinity i Analyzer.
P980040/S111	06/11/2020	O - Normal 180 Day	SENSAR SOFT ACRYLIC UV-LIGHT ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	JOHNSON & JOHNSON SURGICAL VISION, INC.	Approval for modified labeling to reflect the findings of the post-approval study for the Models ZCT300 and ZCT400.
P980049/S135	06/24/2020	N - Normal 180 Day	DEFENDER II MODEL 9201 IMPLANTABLE CARDIOVERTER DEFIBRILLATOR	MICROPORT CRM USA INC.	Approval for alternate hardware components and electronic configurations used on the electronic assembly, the V2.4.6 software update, and labeling updates.

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P980050/S126	06/02/2020	R - Real-Time Proc	MEDTRONIC(R) JEWEL(R) AF 7250 DUAL CHAMBER IMPLANTABLE CARDIOVERTER DEFIBRILLATOR, MODEL 9961 PROGRAMMER APPLICATION SOF	MEDTRONIC INC.	Approval for a change to the lead serial number ink/foil material for select implantable leads.
P010012/S518	06/15/2020	R - Real-Time Proc	CONTAK CD,EASYTRAK, LIVIAN, COGNIS AND ACUITY SPIRIAL AUTOMATIC IMPLANTABLE CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLL	BOSTON SCIENTIFIC CORP.	Approval for Model 3892 Altrua/Insignia/Nexus I Software Support Application v 1.04, Model 3909 Multiple Application Utility v 1.09, Model 3920 Platform Operating System v1.08, Model 3923 Quick Start Application v1.05 software applications of the Model 3300 LATTITUDE Programming System.
P010032/S156	06/05/2020	N - Normal 180 Day	GENESIS AND EON FAMILY NEUROSTIMULATION (IPG) SYSTEMS	ABBOTT MEDICAL	Approval for cybersecurity software updates for the Clinician Programmer (CP) and Patient Controller (PC).
P020012/S036	06/19/2020	S - Special CBE	ARTEFILL, BELLAFILL PMMA COLLAGEN PERMANENT DERMAL FILLER	SUNEVA MEDICAL, INC.	Approval for a revision to the clinician labeling of Bellafill Dermal Filler to include updated safety information based upon post marketing surveillance data.
P020025/S127	06/04/2020	R - Real-Time Proc	EP TECHNOLOGIES EPT-1000 XP RF ABLATION SYSTEM	BOSTON SCIENTIFIC	Approval for a design change to the Control Wire Sleeve of the Blazer Prime HTD and Blazer Prime XP cardiac ablation catheters.
P030004/S017	06/15/2020	O - Normal 180 Day	ONYX LIQUID EMBOLIC SYSTEM	EV3 NEUROVASCULAR	Approval for a labeling change for the Apollo Onyx Delivery Micro Catheter to include the results of the Apollo Onyx Delivery Micro Catheter Post Market Safety Study (APOLLO PMS).
P030005/S197	06/15/2020	R - Real-Time Proc	CONTAK RENEWAL MODELS H125 AND H120 WITH THE MODEL 2865 VERSION 1.8 APPLICATION SOFTWARE	GUIDANT CORP.	Approval for Model 3892 Altrua/Insignia/Nexus I Software Support Application v 1.04, Model 3909 Multiple Application Utility v 1.09, Model 3920 Platform Operating System v1.08, Model 3923 Quick Start Application v1.05 software applications of the Model 3300 LATTITUDE Programming System.
P030035/S178	06/30/2020	N - Normal 180 Day	ANTHEM AND FRONTIER II CRT-P'S	ST. JUDE MEDICAL, INC.	Approval for Avant, Neutrino NxT, Gallant, and Entrant families of ICDs and CRT-Ds; myMerlinPulse mobile application; Merlin PCS 3650 Programmer Software Model 3330 v25.0.1; and Merlin.net MN5000 v7.8.
P030036/S119	06/02/2020	R - Real-Time Proc	MEDTRONIC SELECTSECURE LEAD MODEL 3830	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for a change to the lead serial number ink/foil material for select implantable leads.
P030054/S374	06/30/2020	N - Normal 180 Day	ST JUDE MEDICAL EPIC HF SYSTEM	ST. JUDE MEDICAL	Approval for Avant, Neutrino NxT, Gallant, and Entrant families of ICDs and CRT-Ds; myMerlinPulse mobile application; Merlin PCS 3650 Programmer Software Model 3330 v25.0.1; and Merlin.net MN5000 v7.8.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P040013/S023	06/17/2020	O - Normal 180 Day	GEM 21S (GROWTH-FACTOR ENHANCED MATRIX	LYNCH BIOLOGICS LLC	Approval for change of the supplier from STERIS (formerly Synergy Health) in Swindon, United Kingdom (STERIS Swindon), to the STERIS AST facility located at 9 Apollo Drive, Whippany, New Jersey, United States (STERIS Whippany), for sterilization of the ?-TCP cup component of the GEM21S device.
P050042/S040	06/05/2020	R - Real-Time Proc	ARCHITECT ANTI-HCV ASSAY; ARCHITECT ANTI-HCV CALIBRATOR; ARCHITECT ANTI-HCV CONTROL	ABBOTT LABORATORIES INC	Approval for the release of the updated Alinity software.
P050051/S037	06/05/2020	R - Real-Time Proc	ABBOTT ARCHITECT AUSAB	ABBOTT LABORATORIES INC	Approval for the release of the updated Alinity software.
P060027/S101	06/24/2020	N - Normal 180 Day	OVATIO CRT SYSTEM	MICROPORT CRM USA INC.	Approval for alternate hardware components and electronic configurations used on the electronic assembly, the V2.4.6 software update, and labeling updates.
P060035/S028	06/05/2020	R - Real-Time Proc	ARCHITECT CORE-M REAGENT KIT/ CALIBRATORS/CONTROLS	ABBOTT LABORATORIES	Approval of the release of the updated Alinity software.
P060037/S063	06/18/2020	Y - 135 Review Tra	NEXGEN LPS-FLEX MOBILE AND LPS-MOBILE BEARING KNEE SYSTEM	ZIMMER, INC.	Approval to add Hot Isostatic Pressing (HIP) as an alternate process in the investment casting for NexGen Femoral components (size D, E, and F).
P060040/S076	06/26/2020	N - Normal 180 Day	THORATEC HEARTMATE II LEFT VENTRICULAR ASSIST SYSTEM	THORATEC CORP.	Approval for an alternate 3rd Tier yarn supplier to manufacture the vascular graft components for the HeartMate II and HeartMate 3 Left Ventricular Assist Systems (LVAS).
P070026/S072	06/26/2020	O - Normal 180 Day	CERAMAX CERAMIC HIP SYSTEM	DEPUY ORTHOPAEDICS, INC.	Extension of the final 5-6 years window by 365 days to allow time to collect the primary endpoint as a result of the COVID-19 pandemic.
P080004/S034	06/15/2020	R - Real-Time Proc	HOYA ISPHERIC MODEL YA-60BB INTRAOCULAR LENS	HOYA SURGICAL OPTICS, INC.	Approval for two new IOL models, iSert® models 254 and 255 which are minor modifications of approved parent preloaded IOL iSert® Model 251.
P080023/S031	06/05/2020	R - Real-Time Proc	ARCHITECT CORE REAGENT KIT, ARCHITECT CORE CALIBRATOR AND ARCHITECT CORE CONTROLS	ABBOTT LABORATORIES	Approval of the release of the updated Alinity software.
P100010/S098	06/23/2020	P - Panel Track	ARCTIC FRONT CRYOCATHETER SYSTEM	MEDTRONIC CRYOCATH LP	Approval for the Arctic Front Advance and Arctic Front Advance Pro Cardiac Cryoablation Catheter is indicated for the treatment of drug refractory recurrent symptomatic paroxysmal and persistent atrial fibrillation (episode duration less than 6 months). The Freezor MAX Cardiac Cryoablation Catheter is used as an adjunctive device in the endocardial treatment of paroxysmal and persistent atrial fibrillation (episode duration less than 6 months) in conjunction with the Arctic Front Cryocatheter for the following uses: 1) Gap cryoablation to complete electrical isolation of the pulmonary veins; 2 Cryoablation of focal trigger sites; and 3) Creation of ablation line between the inferior vena cava and the tricuspid valve.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P100049/S027	06/29/2020	Y - 135 Review Tra	LINX REFLUX MANAGEMENT SYSTEM	TORAX MEDICAL	adding a second Hardwell Controlled Environmental Area (CEA).
P110029/S030	06/05/2020	R - Real-Time Proc	ARCHITECT HBSAG QUALITATIVE, QUALITATIVE CONFIRMATORY, CONFIRMATORY MANUAL DILUENT, CALIBRATORS, AND CONTROLS	ABBOTT LABORATORIES	Approval of the release of the updated Alinity software.
P110033/S047	06/12/2020	P - Panel Track	JUVEDERM VOLUMA XC	ALLERGAN	Approval for the Juvéderm Voluma XC for expanding the indications to include chin augmentation. This device is indicated for deep (subcutaneous and/or supraperiosteal) injection for cheek augmentation to correct age-related volume deficit in the mid-face and for augmentation of the chin region to improve the chin profile in adults over the age of 21.
P120006/S035	06/16/2020	O - Normal 180 Day	OVATION ABDOMINAL STENT GRAFT SYSTEM	ENDOLOGIX, INC.	Approval for the Alto Case Selection and Sizing Study post-approval study protocol.
P120008/S013	06/05/2020	R - Real-Time Proc	ABBOTT ARCHITECT AFP ASSAY	ABBOTT LABORATORIES	Approval of the release of the updated Alinity software.
P120017/S021	06/02/2020	R - Real-Time Proc	MODEL 5071 LEAD	MEDTRONIC INC.	Approval for a change to the lead serial number ink/foil material for select implantable leads.
P130005/S029	06/18/2020	N - Normal 180 Day	DIAMONDBACK 360 CORONARY ORBITAL ATHERECTOMY SYSTEM	CARDIOVASCULAR SYSTEMS, INC.	Approval for performing certain manufacturing processes for the 1.25mm Classic Crown OAD assembly internally.
P130008/S052	06/12/2020	O - Normal 180 Day	INSPIRE II UPPER AIRWAY STIMULATOR	INSPIRE MEDICAL SYSTEMS	Approval of the protocol for the post-approval study (PAS) protocol.
P130024/S035	06/26/2020	R - Real-Time Proc	LUTONIX DRUG COATED BALLOON PTA CATETER	LUTONIX	Approval for an extension to the shelf-life of the 4-6x220 mm and the 7x80-220 mm balloon sizes.
P130026/S058	06/05/2020	R - Real-Time Proc	TACTICATH QUARTZ SET	ST. JUDE MEDICAL	Approval for modification to the counterbore depth specification.
P140003/S065	06/26/2020	Y - 135 Review Tra	IMPELLA 2.5 SYSTEM	ABIOMED, INC.	Approval for adding Dexter Magnetic Technologies as a supplier for the motor magnet component for the Impella 2.5, Impella CP, and Impella CP with SmartAssist.
P140005/S004	06/07/2020	S - Special CBE	GENVISC 850	ORTHOGENRX,INC	Approval for revision of the instructions for administration of GenVisc 850 to help prevent any leakage of the product during administration.
P140009/S052	06/05/2020	N - Normal 180 Day	BRIO NEUROSTIMULATION SYSTEM	ABBOTT MEDICAL	Approval for cybersecurity software updates for the Clinician Programmer (CP) and Patient Controller (PC).
P140026/S014	06/04/2020	O - Normal 180 Day	ENROUTE TRANSCAROTID STENT SYSTEM	SILK ROAD MEDICAL, INC	Approval for the addition of the ROADSTER 2 Post-Approval Study results to the Instructions for Use.
P140029/S022	06/24/2020	N - Normal 180 Day	RESTYLANE REFYNE, RESTYLANE DEFYNE	Q-MED AB	Approval for a new alternative supplier for Lidocaine Hydrochloride (Lidocaine HCl).

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P140033/S050	06/30/2020	N - Normal 180 Day	ASSURITY MRI AND ENDURITY MRI PACEMAKERS, TENDRIL MRI LEAD, MRI ACTIVATOR, MERLIN PCS PROGRAMER SOFTWARE	ST. JUDE MEDICAL, INC.	Approval for Avant, Neutrino NxT, Gallant, and Entrant families of ICDs and CRT-Ds; myMerlinPulse mobile application; Merlin PCS 3650 Programmer Software Model 3330 v25.0.1; and Merlin.net MN5000 v7.8.
P140033/S054	06/26/2020	N - Normal 180 Day	ASSURITY MRI AND ENDURITY MRI PACEMAKERS, TENDRIL MRI LEAD, MRI ACTIVATOR, MERLIN PCS PROGRAMER SOFTWARE	ST. JUDE MEDICAL, INC.	Approval for Accent MRI Pacemaker Models PM1124, PM2124 and PM2224.
P150004/S033	06/05/2020	N - Normal 180 Day	AXIUM NEUROSTIMULATOR SYSTEM	ABBOTT MEDICAL	Approval for cybersecurity software updates for the Clinician Programmer (CP) and Patient Controller (PC).
P150011/S020	06/11/2020	R - Real-Time Proc	PERCEVAL SUTURELESS HEART VALVE	LIVANOVA CANADA CORP.	Approval for labeling changes related to sizing instructions for the Perceval Sutureless Heart Valve.
P150012/S092	06/15/2020	R - Real-Time Proc	IMAGEREADY MR CONDITIONAL PACING SYSTEM AND INGEVITY PACE/SENSE LEAD	BOSTONSCIENTIFIC	Approval for Model 3892 Altrua/Insignia/Nexus I Software Support Application v 1.04, Model 3909 Multiple Application Utility v 1.09, Model 3920 Platform Operating System v1.08, Model 3923 Quick Start Application v1.05 software applications of the Model 3300 LATTITUDE Programming System.
P150012/S095	06/19/2020	O - Normal 180 Day	IMAGEREADY MR CONDITIONAL PACING SYSTEM AND INGEVITY PACE/SENSE LEAD	BOSTONSCIENTIFIC	Approval of the revised protocol for the post-approval study (PAS) referenced above. The PAS protocol has been submitted to comply with the conditions of approval outlined in our approval order for P150012/S083.
P150031/S031	06/29/2020	R - Real-Time Proc	VERCISE DEEP BRAIN STIMULATION (DBS) SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for updated Clinician Programmer (CP) computer and minor updates to the Bionic Navigator Software used with the Vercise¿ Deep Brain Stimulation (DBS) System
P150033/S070	06/17/2020	O - Normal 180 Day	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Approval to pool existing usable M-PREP treadmill test data from the Micra IDE, China IDE, and the Micra rate response study.
P160014/S015	06/18/2020	R - Real-Time Proc	COBRA PZF NANOCOATED CORONARY STENT SYSTEM	CELONOVA BIOSCIENCES, INC.	Approval for a change to the device packaging.
P160015/S004	06/05/2020	O - Normal 180 Day	AED PLUS AND FULLY AUTOMATIC AED PLUS	ZOLL MEDICAL CORPORATION	Approval of the protocol for the post-approval study (PAS) protocol.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P160037/S004	06/12/2020	N - Normal 180 Day	BD ONCLARITY HPV ASSAY	BECTON, DICKINSON AND COMPANY	Approval for changes to labeling to include expansion of the assay reporting claims to include additional high-risk HPV genotypes (beyond HPV 16, 18 and 45). The BD Onclarity HPV Assay is a qualitative in vitro test for the detection of Human Papillomavirus in clinician-collected cervical specimens using an endocervical brush/ spatula combination or broom and placed in a BD SurePath vial. The test utilizes amplification of target DNA by the Polymerase Chain Reaction (PCR) and nucleic acid hybridization for the detection of 14 high-risk (HR) HPV types in a single analysis. The test specifically identifies types 16, 18, 31, 45, 51, and 52 while reporting the other HR HPV types in groups (33/58, 35/39/68, and 56/59/66). The BD Onclarity HPV Assay is indicated for use for routine cervical cancer screening as per professional medical guidelines, including triage of ASC-US cytology, co-testing (or adjunctive screen) with cytology, and HPV primary screening of women to assess the risk for cervical precancer and cancer. Patients should be followed-up in accordance with professional medical guidelines, results from prior screening, medical history, and other risk factors. WARNING The BD Onclarity HPV Assay is NOT intended: 1) For use in determining the need for treatment (i.e., excisional or ablative treatment of the cervix) in the absence of high-grade cervical dysplasia. Patients who are HPV 16, 18 and 45 positive should be assessed for the development of high-grade cervical intraepithelial neoplasia according to current practice guidelines; 2) For women who have undergone hysterectomy with removal of the cervix; and 3) For use with samples other than those collected by a clinician using an endocervical brush/spatula combination or broom and placed in the BD SurePath Preservative Fluid Collection Vial. HPV-negative cancers of the cervix do occur infrequently. No cancer screening test is 100% sensitive. Use of this device for primary cervical cancer screening should be undertaken after carefully considering the performance characteristics put forth in this label, as well as recommendations of professional guidelines. The use of this test has not been evaluated for the management of women with prior ablative or excisional therapy, or who are pregnant, or below age 21, or for the management of transgender individuals.
P160047/S008	06/17/2020	R - Real-Time Proc	AEGEA VAPOR SYSTEM, AEGEA VAPOR PROBE PROCEDURE KIT, AEGEA VAPOR GENERATOR AND AEGEA VAPOR GENERATOR ACCESSORY KIT	AEGEA MEDICAL , INC	Approval for software changes to fix known anomalies identified in P160047/ S006 and to include device-specific user authentication.
P160054/S025	06/26/2020	N - Normal 180 Day	HEARTMATE 3¿ LEFT VENTRICULAR ASSIST SYSTEM	THORATEC CORPORATION	Approval for an alternate 3rd Tier yarn supplier to manufacture the vascular graft components for the HeartMate II and HeartMate 3 Left Ventricular Assist Systems (LVAS).
P160057/S001	06/07/2020	S - Special CBE	TRIVISC	ORTHOGENRX,INC	Approval for revision of the instructions for administration of TriVisc to help prevent any leakage of the product during administration.
P170012/S022	06/10/2020	R - Real-Time Proc	HEMOBLAST¿ BELLOWS	BIOM'UP FRANCE SAS	Approval for modifications to the labeling for the Laparoscopic Applicator component of the HEMOBLAST Bellows.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P170019/S016	06/16/2020	P - Panel Track	FOUNDATIONONE CDX	FOUNDATION MEDICINE, INC.	Approval order to expand the intended use of FoundationOne®CDx (F1CDx) to include high tumor mutational burden (TMB) at the cut-off of greater than or equal to 10 mutations per megabase (mut/Mb) in patients with solid tumors who may benefit from treatment with KEYTRUDA® (pembrolizumab).
P170043/S003	06/01/2020	N - Normal 180 Day	ISTENT INJECT TRABECULAR MICRO-BYPASS SYSTEM (MODEL G2-M-IS)	GLAUKOS CORPORATION	Approval for an optional second Collet Holder Assembly in the Model G2-M-IS injector.
P180029/S022	06/17/2020	R - Real-Time Proc	LOTUS EDGE VALVE SYSTEM	BOSTON SCIENTIFIC CORPORATION	Approval of protocol for shelf life extensions.
P180035/S006	06/25/2020	R - Real-Time Proc	MISIGHT 1 DAY (OMAFILCON A) SOFT (HYDROPHILIC) CONTACT LENSES FOR DAILY WEAR	COOPERVISION, INC.	Approval for a change in refractive index specification.
P180046/S006	06/02/2020	R - Real-Time Proc	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Approval for an update to the Patient Remote software.
P190006/S006	06/02/2020	R - Real-Time Proc	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Approval for an update to the Patient Remote software.
P190008/S003	06/25/2020	O - Normal 180 Day	IN.PACT AV PACLITAXEL-COATED PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY BALLOON CATHETER	MEDTRONIC VASCULAR INC.	Approval for the updated informed consent form addendum for the post-approval study protocol.

Total: 80

30-Day Notice

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N18033/S107	06/01/2020	X - 30-Day Notice	ACUVUE CONTACT LENS	VISTAKON, JOHNSON & JOHNSON VISION PRODUCTS, INC.	Addition of an in-process control point during the manufacture of VISTAKON (senofilcon A) and (etafilcon A) Brand Contact Lenses.
N970012/S178	06/16/2020	X - 30-Day Notice	AMS 700 SERIES PRODUCT LINE AND THE DYNAFLEX INFLATABLE PENILE	BOSTON SCIENTIFIC CORP.	Add a new lid printing machine for the AMS 700 Inflatable Penile Prosthesis (IPP), Ambicor IPP, and AMS 800 AUS (Urinary Control System).

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P830055/S247	06/16/2020	X - 30-Day Notice	LCS(R) TOTAL KNEE SYSTEM	DEPUY, INC.	Addition of an alternate casting site for the ATTUNE Revision Femoral Component material casting process. This change will add the DePuy Synthes Raynham, MA facility in addition to Orchid Orthopedic Solutions, the current external supplier.
P830055/S248	06/15/2020	X - 30-Day Notice	LCS(R) TOTAL KNEE SYSTEM	DEPUY, INC.	Re-sequencing/consolidating manufacturing steps to align the Raynham, USA manufacturing site with the approved Cork, Ireland manufacturing site and the change of the manual box buffing touch-up operation to an optional per the visual inspection to meet the finish drawing specifications.
P840001/S462	06/09/2020	X - 30-Day Notice	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODU LATION	Modification of the final visual inspection procedure.
P860004/S359	06/09/2020	X - 30-Day Notice	MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM	MEDTRONIC INC.	Modification of the final visual inspection procedure.
P890064/S041	06/18/2020	X - 30-Day Notice	VIRATYPE HUMAN PAPILLOMAVIRUS DNA TYPING KIT	QIAGEN GAITHERSBU RG, INC	Alternate supplier for PCB.
P900056/S185	06/16/2020	X - 30-Day Notice	ROTABLATOR(R)	BOSTON SCIENTIFIC CORP.	Modifications to associated acceptance activities/inspections for the supplied infusion hose assembly for Rotalink and Rotapro advancers.
P910077/S179	06/12/2020	X - 30-Day Notice	VENTAK(R) PRX (TM) MODEL 1700,1705 PULSE GENERATOR	BOSTON SCIENTIFIC	Alternate, functionally equivalent manufacturing line for LATITUDE Wave Communicator printed circuit assemblies.
P930031/S067	06/25/2020	X - 30-Day Notice	WALLSTENT(R) TIPS ENDOPROSTHESIS WITH UNISTEP PLUS DELIVERY SYSTEM	BOSTON SCIENTIFIC CORP.	Use of an alternate extrusion line.
P940019/S058	06/25/2020	X - 30-Day Notice	WALLSTENT(R) ILIAC ENDOPROSTHESIS	BOSTON SCIENTIFIC SCIMED, INC.	Use of an alternate extrusion line.
P950020/S108	06/12/2020	X - 30-Day Notice	FLEXATOME CUTTING BALLOON	BOSTON SCIENTIFIC CORP.	Addition of an interface software application to the proximal bond inspection step.
P950022/S133	06/18/2020	X - 30-Day Notice	TVL(TM) LEAD SYSTEM	ST. JUDE MEDICAL, INC.	Inclusion of Abbott SOAL and Abbott RE TEM as alternate test sites; use of a distal subassembly as a surrogate stability test article; and an update to the annual stability protocol.
P950022/S134	06/30/2020	X - 30-Day Notice	TVL(TM) LEAD SYSTEM	ST. JUDE MEDICAL, INC.	Implement previously approved changes to new lead models Durata (7172Q) and Optisure (LDP210Q).
P960009/S375	06/09/2020	X - 30-Day Notice	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Modification of the final visual inspection procedure.
P960013/S112	06/17/2020	X - 30-Day Notice	TENDRIL DX MODEL 1388T & 1388K ENDOCARDIAL PACING LEADS	ST JUDE MEDICAL	Process improvements and changes associated with the optimized drug release/elution test method for batch release and annual stability for OptiSense leads MCRD component manufacturing.

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P960013/S113	06/18/2020	X - 30-Day Notice	TENDRIL DX MODEL 1388T & 1388K ENDOCARDIAL PACING LEADS	ST JUDE MEDICAL	Inclusion of Abbott SOAL and Abbott RE TEM as alternate test sites; use of a distal subassembly as a surrogate stability test article; and an update to the annual stability protocol.
P960016/S083	06/04/2020	X - 30-Day Notice	LIVEWIRE(R) CARDIAC ABLATION SYSTEM	ST. JUDE MEDICAL	Implementation of parametric release as part of the sterilization process at the Midwestern Sterilization Corporation facility.
P960030/S069	06/18/2020	X - 30-Day Notice	PASSIVE PLUS DX ENDOCARDIAL STEROID ELUTING, PASSIVE-FIXATION PACING LEADS	ST. JUDE MEDICAL	Inclusion of Abbott SOAL and Abbott RE TEM as alternate test sites; use of a distal subassembly as a surrogate stability test article; and an update to the annual stability protocol.
P970004/S311	06/09/2020	X - 30-Day Notice	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Modification of the final visual inspection procedure.
P980016/S741	06/08/2020	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Modify final visual inspection requirements for hybrid modules.
P980018/S025	06/30/2020	X - 30-Day Notice	DAKO HERCEPTEST	DAKO DENMARK APS	Changes to mixing process of antibody dilutions.
P980033/S057	06/25/2020	X - 30-Day Notice	WALLSTENT ENDOPROSTHESIS	BOSTON SCIENTIFIC CORPORATION	Use of an alternate extrusion line.
P980035/S627	06/08/2020	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Modify final visual inspection requirements for hybrid modules.
P980035/S630	06/23/2020	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Update the Dadet manufacturing process flows, equipment, settings and configuration at MSO.
P990009/S060	06/02/2020	X - 30-Day Notice	FLOSEAL MATRIX/ FLOSEAL MATRIX HEMOSTATIC SEALANT/ PROCEED HEMOSTATIC SEALANT	BAXTER HEALTHCARE CORP.	Change of a packaging material supplier.
P000006/S056	06/05/2020	X - 30-Day Notice	TITAN INFLATABLE PENILE PROSTHESIS	COLOPLAST CORP.	Add a fixture to the standard cylinder bladder tip cutting manufacturing process for the Titan Inflatable Penile Prosthesis.
P000039/S073	06/04/2020	X - 30-Day Notice	THE AMPLATZER(R) SEPTAL OCCLUDER (ASO) AND THE AMPLATZER EXCHANGE SYSTEM	ABBOTT MEDICAL	Implementation of parametric release as part of the sterilization process at the Midwestern Sterilization Corporation facility.

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P000053/S113	06/16/2020	X - 30-Day Notice	AMS SPHINCTER 800 URINARY CONTROL SYSTEM	BOSTON SCIENTIFIC CORP.	Add a new lid printing machine for the AMS 700 Inflatable Penile Prosthesis (IPP), Ambicor IPP, and AMS 800 AUS (Urinary Control System).
P010015/S436	06/08/2020	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Modify final visual inspection requirements for hybrid modules.
P010015/S437	06/18/2020	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Update the distribution control sorter tool system used for select CRT-P device manufacturing.
P010030/S139	06/17/2020	X - 30-Day Notice	WEARABLE CARDIOVERTER DEFIBRILLATOR (WCD) 2000 "LIFEVEST"	ZOLL MANUFACTURING CORPORATION	Solder paste inspection system for the battery printed circuit assembly.
P010031/S702	06/08/2020	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Modify final visual inspection requirements for hybrid modules.
P010032/S164	06/04/2020	X - 30-Day Notice	GENESIS AND EON FAMILY NEUROSTIMULATION (IPG) SYSTEMS	ABBOTT MEDICAL	Addition of an alternate tier-3 supplier for ASTM Grade-I Titanium material used in the manufacture for implantable pulse generators.
P020024/S064	06/04/2020	X - 30-Day Notice	AMPLATZER DUCT OCCLUDER AND 180 DEGREE DELIVERY SYSTEM	ABBOTT MEDICAL	Implementation of parametric release as part of the sterilization process at the Midwestern Sterilization Corporation facility.
P020025/S128	06/17/2020	X - 30-Day Notice	EP TECHNOLOGIES EPT-1000 XP RF ABLATION SYSTEM	BOSTON SCIENTIFIC	Alternative supplier of the PCBA component used in the BSC IntellaNav XP and IntellaNav MiFi XP ablation catheters.
P030004/S024	06/29/2020	X - 30-Day Notice	ONYX LIQUID EMBOLIC SYSTEM	EV3 NEUROVASCULAR	Moving the braiding and annealing operations for the Onyx Apollo Delivery Micro Catheter from the clean room to a non-controlled environment.
P030009/S096	06/02/2020	X - 30-Day Notice	DRIVER OVER-THE-WIRE, RAPID EXCHANGE, AND MULTI-EXCHANGE CORONARY STENT SYSTEMS	MEDTRONIC IRELAND	Introduction of an upgraded pouch sealer to the manufacturing process.
P030031/S106	06/26/2020	X - 30-Day Notice	BIOSENSE WEBSTER NAVISTAR/CELSIUS THERMO COOL DIAGNOSTIC/ABLATION DEFLECTABLE TIP CATHETERS	BIOSENSE WEBSTER, INC.	Implementation of an automated resistance inspection process.

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P030054/S379	06/18/2020	X - 30-Day Notice	ST JUDE MEDICAL EPIC HF SYSTEM	ST. JUDE MEDICAL	Inclusion of Abbott SOAL and Abbott RE TEM as alternate test sites; use of a distal subassembly as a surrogate stability test article; and an update to the annual stability protocol.
P030056/S017	06/21/2020	X - 30-Day Notice	ADVIA CENTAUR HCV READY PACK REAGENTS, ADVIA CENTAUR HCV QUALITY CONTROL MATERIALS	SIEMENS HEALTHCARE DIAGNOSTICS	Change to adopt the suppliers shelf life.
P040036/S074	06/26/2020	X - 30-Day Notice	NAVISTAR THERMOCOOL DEFLECTABLE DIAGNOSTIC/ABLATION CATHETER	BIOSENSE WEBSTER, INC.	Implementation of an automated resistance inspection process.
P040037/S137	06/03/2020	X - 30-Day Notice	VIABAHN ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,INC	Thermal bond manufacturing aid change.
P040040/S043	06/04/2020	X - 30-Day Notice	AMPLATZER MUSCULAR VSD OCCLUDER	ABBOTT MEDICAL	Implementation of parametric release as part of the sterilization process at the Midwestern Sterilization Corporation facility.
P040045/S114	06/01/2020	X - 30-Day Notice	VISTAKON (SENOFILCON A) CONTACT LENS, CLEAR AND VISIBILITY TINTED WITH UV BLOCKER	VISTAKON, DIVISION OF JOHNSON & JOHNSON VISION CAR	Addition of an in-process control point during the manufacture of VISTAKON (senofilcon A) and (etafilcon A) Brand Contact Lenses.
P040045/S115	06/16/2020	X - 30-Day Notice	VISTAKON (SENOFILCON A) CONTACT LENS, CLEAR AND VISIBILITY TINTED WITH UV BLOCKER	VISTAKON, DIVISION OF JOHNSON & JOHNSON VISION CAR	Qualification of an external supplier used to repackage VISTAKON® (senofilcon A) Brand Contact Lenses.
P050027/S021	06/05/2020	X - 30-Day Notice	KARL STORZ PHOTODYNAMIC DIAGNOSTIC D-LIGHT C (PDD) SYSTEM	KARL STORZ ENDOSCOPY-AMERICA, INC.	Manufacturing change to add a filtered air brush that uses compressed air as an alternative to canned air for cleaning the Tricam Pendulum camera head.
P060011/S022	06/10/2020	X - 30-Day Notice	C-FLEX MODEL 570C INTRAOCULAR LENS (IOL)	RAYNER INTRAOCULAR LENSES LTD.	New equipment to remove milled lenses from the wax that secures them to the arbors.
P060011/S024	06/24/2020	X - 30-Day Notice	C-FLEX MODEL 570C INTRAOCULAR LENS (IOL)	RAYNER INTRAOCULAR LENSES LTD.	Alternative supplier of 0.9% w/v sodium chloride, new tubing for controlled dosing of saline, and a new desktop autoclave for sterilization of new tubing.
P060037/S064	06/05/2020	X - 30-Day Notice	NEXGEN LPS-FLEX MOBILE AND LPS-MOBILE BEARING KNEE SYSTEM	ZIMMER, INC.	The Belco Tray Sealer and Cognex Vision System are being added to the process.
P070026/S074	06/24/2020	X - 30-Day Notice	CERAMAX CERAMIC HIP SYSTEM	DEPUY ORTHOPAEDICS, INC.	Change in Chemical Formulation and Cleaning Detergent for Final Cleaning Process for several Hip components.

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P080006/S148	06/23/2020	X - 30-Day Notice	MEDTRONIC ATTAIN ABILITY MODEL 4196 LEAD	MEDTRONIC INC.	Implement a tip grinding process improvement for helix components.
P080025/S206	06/09/2020	X - 30-Day Notice	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Modification of the final visual inspection procedure.
P100010/S105	06/18/2020	X - 30-Day Notice	ARCTIC FRONT CRYOCATHETER SYSTEM	MEDTRONIC CRYOCATH LP	Add an alternate supplier, Medtronic Puerto Rico Operations Co., Villalba, for the manufacture of the Arctic Front Advance Pro Guidewire Lumen (GWL) subassembly.
P100010/S106	06/25/2020	X - 30-Day Notice	ARCTIC FRONT CRYOCATHETER SYSTEM	MEDTRONIC CRYOCATH LP	Minor manufacturing changes to the Artic Front Advance Pro Cryoablation catheters to improve manufacturing efficiency of the balloon assembly.
P100018/S027	06/29/2020	X - 30-Day Notice	PIPELINE EMBOLIZATION DEVICE	MICRO THERAPEUTICS, INC. D/B/A EV3 NEUROVASCULAR	Moving the braiding operation for the Pipeline Flex Embolization Device from the clean room to a non-controlled environment.
P100020/S052	06/24/2020	X - 30-Day Notice	COBAS HPV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Reagent manufacturing scale-up.
P100033/S011	06/08/2020	X - 30-Day Notice	PROGENSA PCA3 ASSAY	GEN-PROBE INCORPORATED	Manufacturing scale-up for reagents.
P100042/S030	06/11/2020	X - 30-Day Notice	APTIMA HPV ASSAY	GEN-PROBE INCORPORATED	Scale-up of reagents.
P100047/S162	06/03/2020	X - 30-Day Notice	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Changes to implement a new Multipart Fixture, Software Program, and a Controller Burn-in Data Verification Spreadsheet at Receiving Inspection of the HVAD System as part of a Corrective and Preventive Action (CAPA).
P100047/S164	06/22/2020	X - 30-Day Notice	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Implementation of updates to the inspection methodologies for components of the HVAD system (Front and Rear Ceramic Discs).
P110010/S179	06/09/2020	X - 30-Day Notice	PROMUS ELEMENT PLUS EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Automation of the visual inspection for evaluating the packaging seal width.
P110016/S069	06/04/2020	X - 30-Day Notice	THERAPY COOL PATH DUO/ SAFIRE BLU DUO ABLATION CATHETER AND IBI 1500T9-CP V1.6 CARDIAC ABLATION GENERATOR	ST. JUDE MEDICAL, INC. (IRVINE BIOMEDICAL)	Implementation of parametric release as part of the sterilization process at the Midwestern Sterilization Corporation facility.

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P120007/S027	06/11/2020	X - 30-Day Notice	APTIMA HPV 16 18/45 GENOTYPE ASSAY	GEN-PROBE INCORPORATED	Scale-up of reagents.
P120021/S018	06/04/2020	X - 30-Day Notice	AMPLATZER PFO OCCLUDER	ABBOTT MEDICAL	Implementation of parametric release as part of the sterilization process at the Midwestern Sterilization Corporation facility.
P130006/S076	06/03/2020	X - 30-Day Notice	GORE VIABAHN ENDOPROSTHESIS AND ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE	W.L. GORE & ASSOCIATES,INC	Thermal bond manufacturing aid change.
P130008/S053	06/18/2020	X - 30-Day Notice	INSPIRE II UPPER AIRWAY STIMULATOR	INSPIRE MEDICAL SYSTEMS	Software update (Version 2.0) to the Hybrid Test System software and new Hybrid Test System hardware equipment for testing of the Model 3028 Implantable Pulse Generator.
P130017/S041	06/15/2020	X - 30-Day Notice	COLOGUARD	EXACT SCIENCES CORPORATION	Manufacturing changes to tube assembly.
P130021/S077	06/11/2020	X - 30-Day Notice	MEDTRONIC COREVALVE SYSTEM	MEDTRONIC COREVALVE LLC	Manufacturing site addition for the supplier of the primary packaging component for the Evolut R, Evolut PRO, and Evolut PRO+ Transcatheter Aortic Valves.
P130021/S078	06/26/2020	X - 30-Day Notice	MEDTRONIC COREVALVE SYSTEM	MEDTRONIC COREVALVE LLC	Update to the pouch sealer for the EnVeo R, EnVeo PRO, and Evolut PRO+ Delivery Catheter Systems and Evolut R/PRO/PRO+ Loading Systems.
P130026/S061	06/04/2020	X - 30-Day Notice	TACTICATH QUARTZ SET	ST. JUDE MEDICAL	Implementation of parametric release as part of the sterilization process at the Midwestern Sterilization Corporation facility.
P140009/S060	06/04/2020	X - 30-Day Notice	BRIO NEUROSTIMULATION SYSTEM	ABBOTT MEDICAL	Addition of an alternate tier-3 supplier for ASTM Grade-I Titanium material used in the manufacture for implantable pulse generators.
P140026/S015	06/01/2020	X - 30-Day Notice	ENROUTE TRANSCAROTID STENT SYSTEM	SILK ROAD MEDICAL, INC	Updates to the software and mechanical components of the control system for Vessel 2 and Vessel 4 at the Steris, El Paso, TX ethylene oxide sterilization facility.
P140028/S060	06/12/2020	X - 30-Day Notice	INNOVA VASCULAR SELF-EXPANDING STENT WITH DELIVERY SYSTEM	BOSTON SCIENTIFIC CORPORATION	Removal of a delivery system process cure time.
P140032/S056	06/09/2020	X - 30-Day Notice	IMPLANTABLE SYSTEM FOR REMODULIN	MEDTRONIC, INC.	Modification of the final visual inspection procedure.
P140033/S059	06/18/2020	X - 30-Day Notice	ASSURITY MRI AND ENDURITY MRI PACEMAKERS, TENDRIL MRI LEAD, MRI ACTIVATOR, MERLIN PCS PROGRAMER SOFTWARE	ST. JUDE MEDICAL, INC.	Inclusion of Abbott SOAL and Abbott RE TEM as alternate test sites; use of a distal subassembly as a surrogate stability test article; and an update to the annual stability protocol.
P150001/S086	06/25/2020	X - 30-Day Notice	MINIMED 630G SYSTEM WITH SMARTGUARD(TM)	MEDTRONIC MINIMED	Addition of a new piece of manufacturing equipment for CGM sensor coating.

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P150003/S062	06/09/2020	X - 30-Day Notice	SYNERGY EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Automation of the visual inspection for evaluating the packaging seal width.
P150004/S039	06/04/2020	X - 30-Day Notice	AXIUM NEUROSTIMULATOR SYSTEM	ABBOTT MEDICAL	Addition of an alternate tier-3 supplier for ASTM Grade-I Titanium material used in the manufacture for implantable pulse generators.
P150005/S056	06/04/2020	X - 30-Day Notice	BLAZER OPEN-IRRIGATED ABLATION CATHETER	BOSTON SCIENTIFIC CORP.	Add an alternate supplier (RMS) for the proximal insert component used in manufacturing of the ablation catheters.
P150033/S073	06/02/2020	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Align the manufacturing of the Micra AV Transcatheter Pacing System with previously approved changes.
P150033/S074	06/08/2020	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Modify final visual inspection requirements for hybrid modules.
P160007/S036	06/25/2020	X - 30-Day Notice	GUARDIAN CONNECT SYSTEM	MEDTRONIC MINIMED	Addition of a new piece of manufacturing equipment for CGM sensor coating.
P160017/S085	06/25/2020	X - 30-Day Notice	MINIMED 670G SYSTEM	MEDTRONIC MINIMED, INC.	Addition of a new piece of manufacturing equipment for CGM sensor coating.
P160022/S018	06/11/2020	X - 30-Day Notice	X SERIES®, R SERIES®, AED PRO®, AED 3¿ BLS PROFESSIONAL DEFIBRILLATORS, PRO-PADZ RADIOTRANSPARENT ELECTRODE, SUREPOWER ¿ BATTERY PACK, SUREPOWER II¿ BATTERY PACK, AED PRO® NON-RECHARGEABLE LITHIUM BATTERY PACK, AED 3 ¿ BATTERY PACK, SUREPOWER¿ CHARGER, AND SUREPOWER ¿ SINGLE BAY CHARGER	ZOLL MEDICAL CORPORATION	Add an additional manufacturing site for a supplier of printed circuit boards for the X Series and Propaq MD.
P160026/S019	06/18/2020	X - 30-Day Notice	LIFEPAK 1000 DEFIBRILLATOR, LIFEPAK 20 DEFIBRILLATOR/ MONITOR, LIFEPAK 20E DEFIBRILLATOR/ MONITOR, LIFEPAK 15 MONITOR/DEFIBRILLATOR, LIFEPAK 12 DEFIBRILLATOR/ MONITOR	PHYSIO-CONTROL. INC.	Update to software and hardware associated with the manufacturing of the Noninvasive Blood Pressure (NIBP) module, a component of the LIFEPAK 15 monitor/defibrillator.

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P160032/S006	06/04/2020	X - 30-Day Notice	LIFELINE/REVIVER DDU-100, LIFELINE/ REVIVER AUTO DDU-120, LIFELINE/REVIVER VIEW DDU-2300, LIFELINE/ REVIVER VIEW AUTO DDU-2200, LIFELINE/ REVIVER ECG DDU-2450, AND LIFELINE/REVIVER ECG+ DDU-2475 AUTOMATED EXTERNAL DEFIBRILLATORS	DEFIBTECH, LLC	Addition of a thermal conditioning and screening process step during DDU-100 and DDU-2000 manufacturing.
P160032/S007	06/23/2020	X - 30-Day Notice	LIFELINE/REVIVER DDU-100, LIFELINE/ REVIVER AUTO DDU-120, LIFELINE/REVIVER VIEW DDU-2300, LIFELINE/ REVIVER VIEW AUTO DDU-2200, LIFELINE/ REVIVER ECG DDU-2450, AND LIFELINE/REVIVER ECG+ DDU-2475 AUTOMATED EXTERNAL DEFIBRILLATORS	DEFIBTECH, LLC	Implementation of a replacement furnace that is used in the manufacture of a diode component used in the device circuit boards.
P160054/S030	06/13/2020	X - 30-Day Notice	HEARTMATE 3¿ LEFT VENTRICULAR ASSIST SYSTEM	THORATEC CORPORATIO N	Add an alternate supplier for the HeartMate 3 pump getter.
P170023/S001	06/02/2020	X - 30-Day Notice	BULKAMID URETHRAL BULKING SYSTEM	CONTURA INTERNATION AL A/S	Modifications to the introducer sheath.
P170030/S006	06/15/2020	X - 30-Day Notice	ORSIRO SIROLIMUS ELUTING CORONARY STENT SYSTEM	BIOTRONIK, INC	Test procedure updates by the drug supplier of the sirolimus used for the Orsiro Sirolimus Eluting Coronary Stent System.
P180011/S032	06/12/2020	X - 30-Day Notice	ELUVIA DRUG-ELUTING VASCULAR STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Removal of a delivery system process cure time.
P180029/S024	06/11/2020	X - 30-Day Notice	LOTUS EDGE VALVE SYSTEM	BOSTON SCIENTIFIC CORPORATIO N	Transfer inspection of several components of the Lotus Edge Valve delivery system to the respective suppliers.

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P190018/S004	06/16/2020	X - 30-Day Notice	CLAREON ASPHERIC HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL), CLAREON TORIC ASPHERIC HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL), CLAREON ASPHERIC HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL) WITH THE AUTONOME PRE-LOADED DELIVERY SYSTEM, CLAREON TORIC ASPHERIC HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL) WITH THE AUTONOME PRE-LOADED DELIVERY SYSTEM	ALCON RESEARCH, LTD.	Alternate second supplier of AutonoMe drive mechanism components.
P190025/S002	06/09/2020	X - 30-Day Notice	ALINITY M HCV	ABBOTT MOLECULAR, INC.	Manufacturing change to increase the fill volume of Activation Reagent in the Alinity m HCV ACT TRAY 2.

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