DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

MEDICAL DEVICE DE NOVO CLASSIFICATION PROCESS

Docket No. FDA-2018-N-0236

Preliminary Regulatory Impact Analysis

Initial Regulatory Flexibility Analysis

Unfunded Mandates Reform Act Analysis

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I. Introduction and Summary

A. Introduction

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, Executive Order 13771, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 13771 requires that the costs associated with significant new regulations "shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations." We believe that this proposed rule is a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because small entities affected by this proposed rule would incur very small one-time costs to read and understand the rule, we propose to certify that the proposed rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $150

million, using the most current (2017) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would not result in an expenditure in any year that meets or exceeds this amount.

The proposed rule, if finalized, would clarify and create a more efficient De Novo classification process by specifying: (1) what medical devices are eligible for the De Novo classification process; (2) what information manufacturers must provide in De Novo requests; and (3) how to organize these data. By clarifying and making more efficient these requirements, we expect the proposed rule, if finalized, could reduce the time and costs associated with reviewing De Novo requests. Moreover, the proposed rule, if finalized, would allow us to refuse to accept inappropriate and deficient De Novo requests, and require us to protect the confidentiality of certain data and information submitted with a request until we issue an order granting the request. We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the proposed rule.

B. Summary of Costs and Benefits

The proposed rule, if finalized, would clarify the De Novo classification process for certain medical devices to obtain marketing authorization as class I or class II devices, rather than remaining automatically designated as class III devices under the FD&C Act. Table 1 summarizes our estimate of the annualized costs and the annualized benefits of the proposed rule.

Table 1. Summary of Benefits, Costs and Distributional Effects of the Proposed Rule ($ millions)

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Benefits					2016	7%	10 years	

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
	Annualized Monetized $millions/year				2016	3%	10 years	
	Annualized Quantified				2016	7%	10 years	
					2016	3%	10 years	
	Qualitative							
Costs	Annualized Monetized $millions/year	$0.04	$0.0	$0.08	2016	7%	10 years	
		$0.02	$0.0	$0.03	2016	3%	10 years	
	Annualized Quantified				2016	7%	10 years	
					2016	3%	10 years	
	Qualitative							
Transfers	Federal Annualized Monetized $millions/year				2016	7%	10 years	
					2016	3%	10 years	
		From:			To:			
	Other Annualized Monetized $millions/year				2016	7%	10 years	
					2016	3%	10 years	
		From:			To:			
Effects	State, Local or Tribal Government: None Small Business: None Wages: None Growth: None							

In line with Executive Order 13771, in Table 2 we estimate present and annualized values of costs and cost-savings over an infinite time horizon.

Table 2. Executive Order 13771 Summary Table (in $ million 2016 dollars over an infinite time horizon)

	Lower Bound (7%)	Primary (7%)	Upper Bound (7%)	Lower Bound (3%)	Primary (3%)	Upper Bound (3%)
Present Value of Costs	$0.0	$0.6	$1.1	$0.0	$0.6	$1.1
Present Value of Cost-Savings	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Present Value of Net Costs	**$0.0**	**$0.6**	**$1.1**	**$0.0**	**$0.6**	**$1.1**
Annualized Costs	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Annualized Cost-Savings	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Annualized Net Costs	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**

II. Preliminary Regulatory Impact Analysis

A. Market Failure Requiring Federal Regulatory Action

The Food and Drug Administration Modernization Act of 1997 (FDAMA) gave us the authority to classify certain novel devices under the De Novo classification process and the 2012 Food and Drug Administration Safety and Innovation Act (FDASIA) removed the requirement that device manufacturers first obtain a not substantially equivalent (NSE) determination for a novel device to submit a De Novo request. In 2016, the 21st Century Cures Act further modified the De Novo classification process to remove the 30-day requirement to submit a De Novo request when a medical device manufacturer receives a NSE determination. Although we have issued guidance to industry about our current interpretation of statutes related to the De Novo classification process, we created an institutional failure by not issuing rulemaking to implement the provisions of the statutes.

The proposed rule, if finalized, would correct this institutional failure and provide the medical device industry with sufficient information about the regulatory requirements of the De

Novo classification process for certain novel devices and would provide FDA with the authority to refuse deficient De Novo requests, creating an incentive to comply with the requirements of the De Novo classification process. The proposed rule also explicitly protects the confidentiality of the data and other information prior to granting the De Novo request, which creates greater assurance that submitting data and other information would not prematurely jeopardize any market advantage. Not understanding the De Novo classification process, or perhaps not trusting the process to protect their data and other information, might lead some in the industry to either not use the De Novo process or to unnecessarily submit premarket notifications (referred to as 510(k)s) prior to submitting a De Novo request. Submitting 510(k)s adds an unnecessary cost for device manufacturers seeking marketing authorization of certain novel devices and for us to review the inappropriate 510(k)s.

B. Background

FDAMA provided FDA with the authority for the De Novo classification process and FDASIA modified the De Novo classification process to remove the requirement that manufacturers provide evidence that their device was NSE to a predicate device. Prior to FDASIA, manufacturers would submit a 510(k) to receive a determination that their device was NSE, and then submit a De Novo request. FDASIA eliminated the need for manufacturers to submit a 510(k) before submitting a De Novo request. When no legally marketed device upon which to base a determination of substantial equivalence exists, manufacturers can submit a De Novo request without first receiving an NSE determination on a 510(k) notification.

The De Novo classification process was meant to reduce the costs of marketing certain "novel" medical devices statutorily classified into class III, even though the medical devices may meet the statutory definition of a class I or class II device. Although the De Novo classification

process was intended to reduce the costs to obtain marketing authorization of novel devices, after FDASIA we have continued to receive inappropriate 510(k)s. On October 30, 2017, FDA issued a final guidance to provide recommendations on the process for the submission and review of a De Novo request. The guidance provides recommendations for interactions with FDA related to the De Novo classification process, including what information to submit when seeking a path to market via the De Novo classification process. Although we expect this guidance would help the medical device industry better understand the De Novo classification process, our program experience also suggests that we need a regulation to refuse inappropriate De Novo requests and to ensure the confidentiality of the data and other information in a De Novo request. The proposed rule, if finalized, would encourage device manufacturers to use the De Novo classification pathway as intended by statute.

C. Costs of the Proposed Rule – The Time to Learn the Rule

We anticipate that medical device manufacturers likely to use the De Novo classification process would incur costs to learn about the requirements of the rule. In 2017, about 17,000 domestic and foreign medical device manufacturers had registered with us. However, we anticipate that most manufacturers would learn about the rule from trade organizations and from our public communications. Some firms may choose to read the entire rule to fully understand the changes to the De Novo classification process. To estimate the time to read and understand the rule, Department of Health and Human Services (HHS) guidance (Ref. 1) recommends using reading speeds of 200 words per minute to 250 words per minute. The proposed rule has approximately 22,000 words. We estimate the time to learn about the requirements for manufacturers that are

likely to utilize the De Novo classification process would be approximately 2 hours (= 22,000 words / 200 words per minute / 60 minutes per hour).

To estimate the cost of a manager's time to read the rule, we use data on the median hourly wage for a General and Operations Manager (occupation code 11-1021) in medical equipment and supplies manufacturing (North American Industry Classification System code 339100). According to the Bureau of Labor Statistics' National Occupational Employment and Wage Estimates for fiscal year 2016, the median wage for this occupation equals $61.20 per hour (Ref. 2). To account for benefits and overhead, we double this value to $122.40 per hour. (= $61.20 x 2). Thus for affected medical device manufacturers who would likely submit a De Novo request, the per firm one-time cost to read and understand the rule equals about $2,450.

To estimate the number of firms that might read the entire rule, we assume that every future request comes from a different device manufacturer and that these manufacturers would learn about the requirements at the time the rule publishes. Based on previous submissions of De Novo requests, we assume that we might receive up to 300 De Novo requests from 300 unique firms over a 5-year period. We estimate that firms would incur a one-time cost to learn about the rule of about $73,440 (= 300 manufacturers x 2 hours per manufacturer x $122.40 per hour). To capture the costs for device manufacturers less likely to use the De Novo classification process, we assume each registered firm would spend an average of 15 minutes (i.e., 0.25 hour) per manufacturer to understand the general requirements of the rule for a one-time cost of about $520,000 ($520,200 = 17,000 manufacturers per year x 0.25 hour x $122.40 per hour). We estimate the total one-time cost for industry to learn about the rule equals about $593,640 (= $73,440 + $520,200). We ask for comment about our estimates.

D. Benefits of the Proposed Rule

The proposed rule, if finalized, would more fully describe the data and other information required for De Novo requests, which should result in higher quality requests. The proposed rule, if finalized, would also allow us to refuse to accept inappropriate or deficient De Novo Requests. Thus, the rule would reduce the time that we spend reviewing and responding to requests. Reducing the review times and providing clarification regarding the content of a De Novo request should encourage manufacturers to introduce their novel devices into the marketplace sooner, which should increase their profitability and consumer satisfaction, and promote the introduction of more medical devices. As more devices obtain marketing authorization via the De Novo classification process, we anticipate that medical device variety would increase, and over time, incrementally lower health costs. We welcome comment on these assumptions.

1. Fewer Inappropriate, Incomplete or Poor-Quality Submissions

The proposed rule, if finalized, would generate benefits by reducing the effort medical device manufacturers spend preparing inappropriate 510(k)s, incomplete or poor quality De Novo requests, and the time we spend reviewing and processing such submissions and requests. Below we describe qualitatively these potential benefits.

a. Fewer Inappropriate 510(k)s

The proposed rule would better clarify and strengthen the incentives for medical device manufacturers to submit a De Novo classification request without first preparing a 510(k). In the years from 2012 to 2016, we received a total of 223 submissions of 510(k)s related to De Novo requests or approximately 50 inappropriate submissions per year. We do not yet know if the 2017 final guidance will eliminate some or all of these inappropriate 510(k) submissions. If medical

device manufacturers continue submitting inappropriate 510(k)s, we expect that the proposed rule, if finalized, would generate costs savings benefits for the medical device industry and for FDA. The cost savings to industry would equal the average cost to prepare each inappropriate 510(k), multiplied by the annual reduction in the number of these notifications. The cost savings to FDA includes the time we would avoid reviewing and responding to these inappropriate 510(k) submissions. Moreover, the proposed rule, if finalized, would allow us to refuse to accept inappropriate 510(k)s. We would avoid the time to review these submissions. However, we lack sufficient information to quantify this cost savings and request comment on any potential benefits from fewer inappropriate 510(k) submissions. We request comment and data to estimate any potential benefits.

b. Better Quality De Novo Requests

If finalized, the proposed rule would provide the medical device industry with more complete and more detailed instructions about the De Novo classification process. We expect that better information would also reduce the time that our scientists spend reviewing De Novo requests because requests would contain all the necessary materials to start a formal review including only required data from sources that meet our standards. However, we lack sufficient data to estimate how industry will respond to the proposed rule, if finalized. We request comment and data to estimate any potential benefits.

c. Fewer Incomplete De Novo Requests

If finalized, we expect that the proposed rule would reduce the number of incomplete De Novo requests because we would have the authority to refuse to accept incomplete requests. Our experience shows that missing materials or materials that do not support a request are the two most

common reasons for incomplete De Novo requests. For De Novo requests with missing materials, we must spend time to communicate what materials should have been included in the request. For De Novo requests containing unnecessary information, we would spend more time than needed to review and then re-review materials provided to support the requests. However, we lack data to quantify these potential benefits and request comment and data on our assumptions.

2. Faster Introduction of Medical Devices and Increased Medical Device Variety

By more fully specifying the requirements for De Novo requests, we would expect industry to more quickly introduce their novel medical devices to the market. Using standard economic theory, with clearer regulatory requirements we anticipate that industry would benefit from the profit (producer surplus) from the additional time their products are commercially available. We would also expect consumers to obtain consumer satisfaction (consumer surplus) during the additional time the products are commercially available. Reduced time and cost from shorter reviews would also encourage more device manufacturers to use the De Novo classification process, which could lead to a greater variety of medical device for consumers over time. The social cost of the original regulatory burden includes the lost producer and consumer surplus associated with products not being marketed or being marketed with a delay. In the same way that the reduced market quantity generates part of the cost of regulation, when we reduce the regulatory burden, the cost saving must include the surplus gains associated with the increased quantity of products.

Although the economic theory is clear, we lack data for the number of individuals that use the medical devices brought to market under the De Novo classification pathway, the willingness of consumers to pay for faster introduction of novel medical devices, and any other data to help us

measure the change in producer and consumer surplus that the faster introduction of these devices might generate. Recent research indicates there is an increasing demand for medical device variety that would enable patients to choose the treatments that best suit their tastes and preferences (Ref. 3). Although consumers would be willing to pay for their additional satisfaction from greater variety, we are not able to identify any studies estimating the willingness of consumers to pay for increased medical device variety.

With fewer submission errors and more complete data there will be lower costs to introduce novel devices using the De Novo classification process, and we would expect to see an increase in product variety. More product variety should improve the ability of consumers to choose a treatment option that better addresses their health condition, which we anticipate would also improve their consumer satisfaction. We welcome comment on how to more precisely account for these impacts.

E. Summary of the Impacts of the Proposed Rule

The proposed rule, if finalized, would more clearly specify the requirements for De Novo requests, which would reduce the likelihood that medical device manufacturers submit De Novo requests that are more costly than necessary, and reduce our review times for De Novo requests. In Table 5, we present our estimates of the quantified impacts of the rule. Over 10 years, the present value of the net costs range from $0.00 million to $1.13 million with both a 3 percent and 7 percent discount rate. Our primary estimate of the present value of the net costs equals $0.58 million with both a 3 percent and 7 percent discount rate.

Table 5. Summary of Costs and Benefits of the Proposed Rule ($ million discounted over 10 years)

	Primary Estimate	Lower Bound	Upper Bound

Present Value at 7 Percent:			
One-time Costs	$0.58	$0.00	$1.13
Recurring Cost Savings	not quantified	not quantified	not quantified
Net Costs	$0.58	$0.00	$1.13
Annualized Value at 7 Percent			
Costs	$0.04	$0.00	$0.08
Recurring Cost Savings	not quantified	not quantified	not quantified
Net Costs	$0.04	$0.00	$0.08
Present Value at 3 Percent			
One-time Costs	$0.58	$0.00	$1.13
Recurring Cost Savings	not quantified	not quantified	not quantified
Net Costs	$0.58	$0.00	$1.13
Annualized Value at 3 Percent			
Costs	$0.02	$0.00	$0.03
Recurring Cost Savings	not quantified	not quantified	not quantified
Net Costs	$0.02	$0.00	$0.03

F. Uncertainty Analysis

1. Uncertainty about the Cost to Learn the Rule

Some uncertainty exists about the number of device manufacturers that would spend the effort to learn about the rule. If the industry does not show interest in the rule and does not bother to learn about it, they would not incur a cost and would be unlikely to benefit from the De Novo classification process. Alternatively, manufacturers might devote more effort to learn about the De Novo classification process than we estimated. If the average device manufacturer spends 30 minutes rather than the 15 minutes, then we have underestimated these costs. We estimate an upper

bound cost to learn the rule would be approximately $1.26 million (= $122.40 per hour x 0.5 hours per manufacturer x 17,000 manufacturers). We report these estimates as our lower and upper bounds in our summary tables.

2. Uncertainty about the Government Cost Savings

We lack direct evidence about how the medical device industry would respond to a more transparent and predictable De Novo classification process. However, a rational, self-interested manufacturer of a medical device that is eligible for the De Novo classification pathway would utilize the De Novo classification process more frequently if the De Novo classification process has lower costs than an alternative process. We recognize that there is considerable uncertainty about how much a more predictable De Novo classification process would lower costs or how much more frequently manufacturers would use the De Novo classification process. One source of uncertainty in our analysis is the number of inappropriate 510(k) submissions that would no longer be submitted. Our 510(k) model predicts that the experiences of manufacturers matter. Over time as the industry gains experience with the revised requirements, we would expect more correctly prepared submissions.

However, another source of uncertainty concerns the amount of time we would save reviewing higher quality requests. We request comment on potential cost savings from higher quality requests.

III. Initial Small Entity Analysis

We examined the economic implications of the proposed rule as required by the Regulatory Flexibility Act. If a proposed rule, when finalized, would have a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires us to analyze regulatory

options that would lessen the economic effect of the rule on small entities. This proposed rule would impose a very small administrative burden of less than $2,500 on each affect small entity. Because small entities affected by this proposed rule would incur very small one-time costs to read and understand the rule, we propose to certify that the proposed rule will not have a significant economic impact on a substantial number of small entities. This analysis, together with other relevant sections of this document, serves as the proposed regulatory flexibility analysis, as required under the Regulatory Flexibility Act.

IV. References

1. Guidelines for Regulatory Impact Analysis, HHS September 2014, Revised Draft with May 2015 Update
2. Bureau of Labor Statistics. National Occupational Employment and Wage Estimates. Occupational Employment Statistics, General and Operations Manager (North American Industry Classification, NAICS, code 339100) May 2016. https://www.bls.gov/oes/current/naics4_339100.htm, accessed June 29 2017.
3. Ross, Jeffrey, and Ginsburg, Geoffrey. 2003. "The Integration of Molecular Diagnostics with Therapeutics: Implications for Drug Development and Pathology Practice." American Journal of Clinical Pathology 119: 26-36.