Medical Device De Novo Classification Process

0910-0844

SUPPORTING STATEMENT

RIN # 0910-AH53

Terms of Clearance: n/a.

A. Justification

1. Circumstances Making the Collection of Information Necessary

The authorizing statute for this information collection is section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act).

Background:

A device may be classified in class III and be subject to premarket approval (PMA) via several different regulatory vehicles. In accordance with the criteria at section 513(a)(1)(C) of the FD&C Act, FDA may promulgate a regulation classifying, or issue an order reclassifying, a device type into class III based on the risks posed by the device and the inability of general and special controls to provide reasonable assurance of the safety and effectiveness of the device. All particular devices of such a type are considered to be in class III and such devices are not eligible for the De Novo classification process.

Alternatively, devices of a new type that FDA has not previously classified based on the criteria at section 513(a)(1) of the FD&C Act are "automatically" or "statutorily" classified into class III by operation of section 513(f)(1) of the FD&C Act, regardless of the level of risk they pose or the ability of general and special controls to assure safety and effectiveness. This is because, by definition, a new type of device would not be within a type that was on the market before the 1976 Medical Device Amendments or that has since been classified into class I or class II. Thus, there would be no available predicate device.

This second scenario is what Congress targeted when it enacted section 513(f)(2) of the FD&C Act as part of the Food and Drug Administration Modernization Act of 1997 (FDAMA). The process created by this provision, which was referred to in FDAMA as the Evaluation of Automatic Class III Designation, will be referred to as the "De Novo classification process" throughout this guidance document. Congress included this section to limit unnecessary expenditure of FDA and industry resources that could occur if devices for which general controls or general and special controls provide a reasonable assurance of safety and effectiveness were subject to premarket approval under section 515 of the FD&C Act. Section 513(f)(2) of the FD&C Act has allowed manufacturers to submit a De Novo request to FDA for devices "automatically" classified into Class III by

operation of section 513(f)(1). As enacted by FDAMA, to submit a De Novo request, a device first had to be found not substantially equivalent (NSE) to legally-marketed predicate devices through a premarket notification (510(k)). The 21st Century Cures Act of 2016 removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination.

Section 513(f)(2) was modified by section 607 of FDASIA, which created an alternative mechanism for submitting a De Novo request that does not require that a device be reviewed first under a 510(k) and found NSE prior to submission of a De Novo request.

The "Draft Guidance for Industry and Food and Drug Administration Staff – De Novo Classification Process (Evaluation of Automatic Class III Designation)" (the De Novo Program Guidance; October 30, 2017, 82 FR 50144) provides guidance on the process for the submission and review of a De Novo classification request (hereafter a "De Novo request") under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act). FDA issued the guidance to provide updated 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.

Request for revision:

FDA is issuing the proposed rule, "Medical Device De Novo Classification Process," to codify the medical device De Novo classification process under section 513(f)(2) of the FD&C Act. We provide below a revised burden estimate for the De Novo classification process as described in the proposed rule.

Proposed 860.201 explains the purpose of the proposed De Novo Classification regulations and provides the applicability of a De Novo request submission. Proposed 860.223 and 860.234 describe the format and content, respectively, of a De Novo request. Proposed 860.245 describes the conditions under which FDA may refuse to accept a De Novo request. Proposed 860.256(b) provides for supplemental, amendatory, or additional information for a pending De Novo request. Proposed 860.267(a)(4) provides that a requester may submit a written notice to FDA that the De Novo request has been withdrawn.

2. Purpose and Use of the Information Collection

A medical device manufacturer may submit a De Novo request under 513(f)(2) to seek market entry for a new medical device. Section 513(f)(2) was modified by section 607 of FDASIA, which created an alternative mechanism for submitting a De Novo request that does not require that a device be reviewed first under a 510(k) and found "not substantially equivalent" (NSE) prior to submission of a De Novo request. Utilizing the De Novo classification pathway promotes innovation and decreases regulatory burdens. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see 21 U.S.C.

360c(f)(2)(B)(i)). As a result, other device sponsors do not have to submit a De Novo request or PMA in order to market the same type of device unless the new device has a new intended use or technological characteristics that raise different questions of safety or effectiveness (see 21 U.S.C. 360c(i), defining "substantial equivalence"). Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

FDA uses the information in the De Novo request to evaluate whether the medical device may be reclassified from Class III to Class I or II, and if applicable, to determine the general and/or special controls necessary to sufficiently regulate the medical device.

Respondents to this information collection, medical device manufacturers, are private sector or other for-profit businesses.

3. Use of Improved Information Technology and Burden Reduction

For De Novo requests, sponsors must submit at least one valid electronic copy (eCopy). See section 745A(b) of the FD&C Act and FDA's eCopy guidance, "eCopy Program for Medical Device Submissions", available at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf. Therefore, FDA estimates that 100% of the respondents will use electronic means to fulfill the agency's requirement or request.

4. Efforts to Identify Duplication and Use of Similar Information

FDA is the only federal agency responsible for premarket review of medical devices; as such, there is no duplication of effort.

The information related to the De Novo request may, in some cases, overlap with information previously included in a related 510(k) submission for the medical device. Wherever possible, FDA will not require that this information be re-submitted but instead may rely on the 510(k) submission as a reference. Therefore, duplication with other data sources available to FDA is expected to be minimal.

5. Impact on Small Businesses or Other Small Entities

Approximately 95% of U.S. medical device manufacturing establishments have fewer than 500 employees and would, therefore, be considered small businesses.

FDA aids small business by providing guidance, consumer assistance, and information through CDRH Learn training tools, the information posted on FDA's website, and the Division of International and Consumer Education (DICE) within the Center for Devices and Radiological Health. DICE provides technical and non-financial assistance to small manufacturers, through a comprehensive program that includes seminars, workshops, and educational conferences, information materials, contact via email and the use of a toll-free telephone number. Other members of the Center staff are also available to respond to questions.

Additionally, the Manufacturers Assistance Branch in the Center for Biologics Evaluation and Research (CBER) provides assistance and training to industry, including large and small manufacturers and trade associations, and responds to requests for information regarding CBER policies and procedures.

6. Consequences of Collecting the Information Less Frequently

   The frequency of FDA's receipt of De Novo requests is determined by the frequency with which medical device manufacturers submit the requests (i.e., occasionally). Because the information in the De Novo request provides a basis for FDA's decision regarding whether to grant market entry for the subject device, the frequency of the information collection is appropriate. The consequence of collecting the information less frequently would potentially be a delay of market entry for the subject device.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

   There are no special circumstances for this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

   As required by section 3506(c)(2)(B) of the Paperwork Reduction Act of 1995 (PRA), FDA provided an opportunity for public comment on the information collection requirements of the proposed rule that published in the FEDERAL REGISTER of December 7, 2018(83 FR 63127).

9. Explanation of Any Payment or Gift to Respondents

   No payment or gifts will be provided to respondents.

10. Assurance of Confidentiality Provided to Respondents

    Proposed § 860.5(g), Confidentiality and use of data and information submitted in connection with classification and reclassification, states that confidentiality of data and information in a De Novo file is as follows:

    (1) A "De Novo file" includes all data and information from the requester submitted with or incorporated by reference in the De Novo request, any De Novo supplement, or any other related submission relevant to the administrative file, as defined in 21 CFR 10.3(a). Any record in the De Novo file will be available for public disclosure in accordance with the provisions of (proposed) § 860.5 and 21 CFR part 20.

    (2) The existence of a De Novo request may not be disclosed by FDA before an order granting the De Novo request is issued unless it previously has been publicly disclosed or acknowledged by the De Novo requester.

    (3) Before an order granting the De Novo request is issued, data or information contained in the De Novo request is not available for public disclosure, except to the extent the existence of the De Novo request is disclosable under paragraph (2) of this section and such data or information has been publicly disclosed or acknowledged by the De Novo requester.

    (4) After FDA issues an order granting a De Novo request, the data and information in the De Novo request that are not exempt from release under 21 CFR 20.61 are immediately available for public disclosure.

11. Justification for Sensitive Questions

This information collection does not include questions that are of a sensitive nature, such as, sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

Based on our recent experience with the De Novo program, FDA estimates that the average burden per response for a De Novo request is 182 hours. This includes information collection associated with the proposed provisions described in 860.201, 860.223, 860.234, 860.245, and 860.256(b). Based on recent program data and trends, we expect to receive approximately 60 De Novo requests per year.

We estimate that the average burden per response for written notice of withdrawal of a De Novo request, as described in proposed 860.267(a)(4), is 10 minutes. The average burden per response is based on estimates by FDA administrative and technical staff who are familiar with the requirements for submission of a De Novo request, have consulted and advised manufacturers on submissions, and have reviewed the documentation submitted. We expect that we will receive approximately five requests for withdrawal per year.

Table 1—Estimated Annual Reporting Burden

Activity/21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
De Novo request—proposed 860.201, 860.223, 860.234, 860.245, 860.256(b)	60	1	60	182	10,920
Written notice of withdrawal—proposed 860.267(a)(4)	5	1	5	10	50
Total					10,970

12b. Annualized Cost Burden Estimate

To estimate the wage rate for the industry personnel that prepare the De Novo submissions, we used median hourly wage rates from the Bureau of Labor Statistics (BLS) May 2017 National Occupational Employment and Wage Estimates for the Medical Equipment and Supplies Manufacturing industry (North American Industry Classification, NAICS, code 339100) of $62.61.* To account for benefits and overhead, we doubled this value to $125.22 (= $62.61 x 2). Therefore, we estimate that the annualized cost burden is $1,373,663 (rounded) ($125.22 x 10,970 hours).

* Bureau of Labor Statistics. National Occupational Employment and Wage Estimates. Occupational Employment Statistics, General and Operations Managers (North American Industry Classification, NAICS, code 339100, occupation code 11-1021) May 2017. https://www.bls.gov/oes/current/naics4_339100.htm#11-0000, accessed July 27, 2018.

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
General and operations managers	10,970	$125.22	$1,373,663

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no capital or start-up costs associated with this information collection.

The operating and maintenance cost for a De Novo request includes the cost of printing, shipping, and the eCopy. We estimate the cost burden for a De Novo request to be $121.30 ($90 printing + $30 shipping + $1.30 eCopy).

We estimate that printing a submission requires an average of 2 reams of paper, or 1,000 pieces of paper. A piece of paper costs $0.03 per page on average. The cost of printing a single page is $0.06 on average.[1] The average total cost of printing per page is, therefore, $0.09 per page ($0.03 paper + $0.06 printing). Therefore, we estimate that printing an average De Novo request will cost approximately $90.

The Agency's eCopy guidance recommends sending all applications using priority shipping. Using shipping calculators on the websites of the US Postal Service, UPS, and FedEx, FDA finds the shipping cost of a single piece of paper to range from $0.01 to $0.05, with an average of $0.03. The average cost of shipping a full paper copy of submissions is, therefore, $30 (1,000 pages shipped × $0.03 per page).

The least expensive type of eCopy media is a CD, which costs on average $0.25 per CD. DVDs cost $0.48 per unit on average and flash drives cost an average of $2.50 per unit. All forms of eCopy media cost roughly $0.22 to ship. Therefore, the cost per eCopy

[1] Quality Logic, "Cost of Ink Per Page Analysis, United States," available at https://www.qualitylogic.com/wp-content/uploads/2016/07/QualityLogic-Cost-of-Ink-Per-Page-Analysis_US_1-Jun-2012.pdf, June 2012.

ranges from $0.47 to $2.72 per eCopy. If eCopies are one-third CDs, one-third DVDs, and one-third flash drives, the average cost per eCopy is $1.30.

We estimate the cost for a request for withdrawal to be $1 (rounded) ($0.09 printing 1 page + $0.03 shipping + $1.30 eCopy).

The annual cost estimate for De Novo requests is $7,278 (rounded) (60 submissions x $121.30). The annual cost estimate for requests for withdrawal is $5. Therefore, we estimate the total annual operating and maintenance costs of this information collection to be $7,283.

14. Annualized Cost to the Federal Government

Using FDA's Fully Loaded FTE Cost Model (Domestic) for FY 2018, we estimate that the total cost including pay, information and management technology, general and administrative overhead, and rent for a medical device reviewer is $270,305 annually. FDA estimates that an average of 20 full time equivalent employees (FTEs) will review and process De Novo requests and related information. Therefore, the burden to government of this information collection is projected to cost approximately $5,406,100 per year ($270,305 x 20 FTEs).

15. Explanation for Program Changes or Adjustments

In the previously approved ICR (for the De Novo Program guidance), De Novo requests are separated into separate ICs for those submitted under 513(f)(2)(i) (estimated 100-hour burden per response) and those submitted under 513(f)(2)(ii) (estimated 180-hour burden per response), then further separated by those sent to CDRH and those sent to CBER. The approved estimated burden includes the De Novo request and any supplements or amendments to the original submission.

The proposed rule simply provides for De Novo requests without distinguishing between those sent under 513(f)(2)(i) or (f)(2)(ii) of the FD&C Act. We have, therefore, included only one IC for De Novo requests in this ICR revision, the estimated burden for which includes the initial request (purpose and applicability in proposed 860.201), content and format (proposed 860.223 and 860.234), supplements (860.256(b)), and time to ensure that all the proposed format and content requirements are met before submission (860.245).

Because the provisions of proposed 860.245 are not included in the approved burden estimates (associated with the De Novo Program Guidance), we have included an additional 2 hours in the Average Burden per Response for manufacturers to review their De Novo request for compliance with the acceptance criteria described listed in proposed 860.245. Based on our recent experience and the expertise of our subject matter experts, we believe the Average Burden per Response for De Novo requests is approximately 182 hours.

Additionally, based on updated data and trends since the previous approval, we expect to receive approximately 60 De Novo requests per year; an increase of 8 respondents per year.

There is no change to the currently approved burden estimate for "Written notice of withdrawal" of a De Novo request. However, we have updated the name of the IC to indicate that it is now under proposed 860.267(a)(4).

The revisions described above increase the total burden estimate by 3,640 hours.

16. Plans for Tabulation and Publication and Project Time Schedule

No publication of information for statistical use is planned.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

FDA will display the OMB expiration date as required by 5 CFR 1320.5.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.