UNITED STATES FOOD & DRUG ADMINISTRATION

Medical Device De Novo Classification Process

OMB Control No. 0910-0844 - Revision

RIN No. 0910-AH53

SUPPORTING STATEMENT – **Part A: Justification**

1. Circumstances Making the Collection of Information Necessary

This information collection implements Food and Drug Administration (FDA, the agency – us or we) regulations and information collection discussed in associated guidance. Sections 201, 513, 701, 704 of the Federal Food, Drug, and Cosmetic (FD&C Act) (21 U.S.C. 321(h), 360c(a) and (f), 371(a), and 374) establish a comprehensive system for the regulation of medical devices intended for human use. Section 513(f)(2) (21 U.S.C. 360c(f)(2)) provides for a "De Novo" classification process, most recently amended by section 3101 of the 21st Century Cures Act (Pub. L. 114-255). The final rule "*Medical Device De Novo Classification Process*" (86 FR 54826), establishes 21 CFR part 860, **new subpart D** (§§ 860.200 through 860.260) to implement provisions in section 513(f)(2) of the FD&C Act. The new regulations govern format and content elements for De Novo device classification requests, as well as withdrawal of the requests, and explain FDA procedures for acceptance, review, and granting or denying a request. In sum, the regulations provide that:

- A person may submit a De Novo request after submitting a 510(k) and receiving a not substantially equivalent (NSE) determination.
- A person may also submit a De Novo request without first submitting a 510(k), if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence (SE).
- FDA will classify devices according to the classification criteria in the FD&C Act. FDA classifies devices into class I (general controls) if there is information showing that the general controls of the FD&C Act are sufficient to reasonably assure safety and effectiveness; into class II (special controls) if general controls, by themselves, are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide such assurance; and into class III (premarket approval) if there is insufficient information to support classifying a device into class I or class II and the device is a life-sustaining or life-supporting device or is for a use which is of substantial importance in preventing impairment of human health or presents a potential unreasonable risk of illness or injury.
- Devices will be classified by FDA by written order.
- A De Novo request includes administrative information, regulatory history, device description, classification summary information, benefits and risks of device use, and performance data to demonstrate reasonable assurance of safety and effectiveness.
- FDA may refuse to accept a De Novo request that is ineligible or that is not sufficiently complete to permit a substantive review.

- After a De Novo request is accepted, FDA will begin a substantive review of the De Novo request that may result in either FDA requesting additional information, issuing an order granting the request, or declining the De Novo request.
- FDA may decline a De Novo request if, among other things, the device is ineligible or insufficient information is provided to support De Novo classification.

In addition to regulatory requirements set forth in 21 CFR part 860, **new subpart D**, we updated the guidance document entitled, "*Acceptance Review for De Novo Classification Requests*," to communicate our thinking on criteria set out in 21 CFR part 860.230, in assessing whether a De Novo request should be accepted for substantive review. The guidance document includes an "*Acceptance Checklist*" to assist respondents in this regard. Also, the guidance document fulfils certain FDA Medical Device User Fee performance goals, as discussed in the agency's current MDUFA Commitment Letter found on our website.

We therefore request OMB approval for the information collection provisions now established in 21 CFR part 860, subpart D; and for the information collection discussed in the referenced guidance document.

2. Purpose and Use of the Information Collection

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

3. Use of Improved Information Technology and Burden Reduction

As required by statute and applicable regulations, submissions are required electronically and we assume all respondents will use electronic means to satisfy the information collection.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

We assume up to 99 percent of firms expected to respond to this information collection are small businesses as defined by the U.S. Small Business Administration. (Final Regulatory Impact Analysis at https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations.) However, we do not believe the information collection poses any undue burden on these entities. 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 Industry 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 information collection schedule is consistent with statutory and regulatory requirements.

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), we included an analysis of the information collection provisions associated with the rulemaking and provided opportunity for public comment in the Federal Register of December 7, 2018 (83 FR 63127). A number of comments were received relating to substantive aspects and are discussed in Section V of the final rule: *Comments on the Proposed Rule and FDA's Response*. None of the comments suggested we revise our burden estimate. Comments and responses relating to information collection are described in the following subsections: V.B (general comments); section V.D (information disclosure); V.F, (definitions); V.G, (format); V.H (content); V.I (acceptance criteria); V.J (criteria for granting or declining a request); and V.K (De Novo classification process for combination products).

9. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments or gifts associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

In preparing this supporting statement, we consulted our Privacy Office to ensure appropriate handling of information collected. Although personally identifiable information (PII) is collected, the data elements are for business contact purposes only and include individuals' names, work mailing address, work telephone number and work email address. We have determined, therefore, that although PII is collected, it is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Privacy Act do not apply. Specifically, FDA does not use name or any other personal identifier to retrieve records from the information collected. FDA also minimized the PII to be collected to protect the privacy of the individuals.

Information provided under this collection is handled in a manner to comply with the FDA regulations on public information in 21 CFR part 20. Data will be kept private to the fullest

extent allowed by law. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1)-(b)(9)). One such provision, 5 U.S.C. 552(b)(4), exempts "trade secrets and commercial or financial information that is privileged or confidential" from the requirement of public disclosure. Section 520(c) of the FD&C Act prohibits FDA from disclosing any information exempted from public disclosure under 5 U.S.C. 552(b)(4).

11. Justification for Sensitive Questions

The collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

Table 1.—Estimated Annual Reporting Burden

21 CFR Part 860, Subpart D; Information Collection Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
§§ 860.210, 860.220, 860.230; De Novo requests – format, content, and acceptance elements	68	1	68	182 hours	12,376
§ 860.230; FDA acceptance of request (*GFI Acceptance Checklist*)[1]	68	1	68	-	-
§ 860.250; withdrawal of request	5	1	5	0.17 (10 mins.)	1
TOTAL			73		12,377

1. FDA assumes activities associated with review of the Acceptance Checklist are included in burden for submission of requests captured in row 1.

Based on our experience with the De Novo program, we assume an average burden of 182 hours per request and estimate 68 submissions annually. We account for burden manufacturers may incur to review their De Novo requests for compliance with 860.230 in our estimate of burden associated with completing a request. The guidance document entitled, "*Acceptance Review for De Novo Classification Requests*" includes an *Acceptance Checklist* that was developed to assist respondents in this regard. Similarly, based on our experience with the information collection and informal feedback from industry, we assume an average burden of 10 minutes (0.17 hours) per notification of withdrawal of a request and estimate five requests for withdrawal will be submitted annually.

12b. Annualized Cost Burden Estimate

To estimate costs to respondents, we assume a wage rate for the labor category "*General and Operations Managers*"* and doubled this figure to account for benefits and overhead ($71.68 x 2=$143). We then multiplied this wage rate by the estimated annual burden hours to calculate a total annualized cost burden of $1,769,911 (rounded) ($143 x 12,377 hours).

* Bureau of Labor Statistics. National Occupational Employment and Wage Estimates. Occupational Employment Statistics (North American Industry Classification, NAICS, code 339100, occupation code 11-1021) May 2020. https://www.bls.gov/oes/current/naics4_339100.htm#11-0000.

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
General and Operations Managers	12,377	$143/hour	$1,769,911

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

Section § 860.210 requires that each De Novo request be submitted as a single version in electronic format. The least expensive type of eCopy media is a CD, averaging $0.25 per CD; DVDs cost an average of $0.48 per unit; and flash drives cost an average of $2.50 per unit. We recommend respondents use priority shipping and assume average costs of $1.30 per request or withdrawal based on current US Postal Service, UPS, and FedEx service rates. Multiplying this figure by the estimated number of annual submissions, we assume operational costs of $95 annually (rounded).

14. Annualized Cost to the Federal Government

We use FDA's Fully Loaded FTE Cost Model (Domestic) for FY 2020 to assume an annual salary cost of $281,225 for a medical device reviewer, and multiply that figure by 20 FTE allocations to determine an annual cost to the Federal government of $5,626,100 ($281,225 x 20 FTEs).

15. Explanation for Program Changes or Adjustments

The information collection includes program changes and adjustments. Consistent with estimates found in our analysis of impacts for RIN 0910-AH53, we have increased our estimate of the total number of respondents since last OMB review and approval. Also, the burden we previously attributed to guidance instruction regarding De Novo classification requests and withdrawals, we now attribute to requirements found in agency regulations. However, in our estimated burden per response for a De Novo request, we continue to account for burden that may be associated with completion of the Acceptance Checklist. Finally, we have corrected an inadvertent error found in our proposed rulemaking. Cumulatively, these changes and adjustments result in an overall annual increase of burden by 1,647 hours and decrease of responses by 112.

16. Plans for Tabulation and Publication and Project Time Schedule

The information collected will not be published or tabulated.

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

As required by the PRA and consistent with established agency practice, FDA will publish a notice in the Federal Register announcing OMB approval of information collection associated with guidance documents included in this information collection. The notice will inform respondents of the OMB control number and current expiration date. However, because agency guidance documents are more frequently being accessed electronically, we are making technological updates to display the expiration date by linking to approval information found at https://www.reginfo.gov/public/. We intend to include the OMB control number and expiration date on the guidance document landing page, allowing those who download the document an easily identifiable option to view this information. This also allows the agency to more easily update the expiration date upon renewal and/or revision of OMB approval of associated information collection. We are taking this approach to improve compatibility with current website platforms utilized by FDA.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.