United States Food and Drug Administration

De Novo Classification Process (Evaluation of Automatic Class III Designation)

OMB Control No. 0910-0844 -- EXTENSION

SUPPORTING STATEMENT

Part A: Justification

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA, the agency – us or we) regulations and information collection discussed in associated guidance.

Sections 201(h), 513(a) and (f), 701(a), and 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) of the FD&C Act 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) established 21 CFR part 860, subpart D (§§ 860.200 through 860.260) to implement provisions in section 513(f)(2) of the FD&C Act. These 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.

There are two options to submit a De Novo request for FDA to make a risk-based evaluation for classification of a device into class I or class II, including (1) after receiving a high-level not substantially equivalent (NSE) determination (that is, no predicate, new intended use, or different technological characteristics that raise different questions of safety and effectiveness) in response to a 510(k) submission, and (2) upon the requester's determination that there is no legally marketed device upon which to base a determination of substantial equivalence (therefore without first submitting a 510(k) and receiving a high-level NSE determination).

FDA's guidance for industry and FDA staff, "*De Novo Classification Process (Evaluation of Automatic Class III Designation)*" provides guidance on the process for the submission and review of a De Novo classification request under section 513(f)(2) of the FD&C Act, also known as the De Novo classification process. This process provides a pathway to class I or class II classification for medical devices for which general controls or general and special controls provide a reasonable assurance of safety and effectiveness, but for which there is no legally marketed predicate device.

In addition to regulatory requirements set forth in 21 CFR part 860, subpart D, the guidance document entitled "*Acceptance Review for De Novo Classification Requests*" communicates 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.

The guidance document "*Electronic Submission Template for Medical Device De Novo Requests*," provides the standards for the submission of De Novo Requests by electronic format, a timetable for establishment of these standards, and criteria for waivers of and exemptions from the requirements to meet a statutory requirement. This guidance is also intended to represent one of several steps in meeting FDA's commitment to the development of electronic submission templates to serve as guided submission preparation tools for industry to improve submission consistency and enhance efficiency in the review process.

The proposed collections of information are necessary to satisfy the previously mentioned statutory requirements for administration of this program. We therefore request extension of OMB approval for the information collection provisions found in 21 CFR part 860, subpart D; and for the information collections discussed in the associated guidance documents.

2. Purpose and Use of the Information Collection

FDA uses the information to evaluate whether a 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. Respondents to this information collection are private sector or other for-profit businesses.

3. Use of Improved Information Technology and Burden Reduction

Section § 860.210 requires that each De Novo request be submitted as a single version in electronic format (eCopy) and we assume all respondents will use electronic means to satisfy the information collection. De Novo submissions can be prepared using FDA's electronic Submission Template and Resource (eSTAR) and voluntarily submitted through the CDRH Customer Collaboration Portal (CDRH Portal; https://www.fda.gov/medical-devices/industry-medical-devices/send-and-track-medical-device-premarket-submissions-online-cdrh-portal) or mailed to the FDA. As of October 1, 2025, FDA will require that De Novo Request electronic submissions be provided as described in the guidance document "Electronic Submission Template for Medical Device De Novo Requests" (see also eSTAR Program, https://www.fda.gov/medical-devices/how-study-and-market-your-device/estar-program).

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/economic-impact-analyses-fda-

regulations/medical-device-de-novo-classification-process.) 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

FDA published a 60-day notice for public comment in the Federal Register of May 29,2024 (89 FR 46402). No comments were received.

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 and 21 CFR part 860.5. 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	79	1	79	182 hours	14,378
§ 860.230; FDA acceptance of request (*GFI Acceptance Checklist*)[1]	79	1	79	-	-
§ 860.250; withdrawal of request	5	1	5	0.17 (10 mins.)	1
TOTAL			84		14,379

[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 recent experience with the De Novo program, we assume an average burden of 182 hours per request and estimate 79 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 ($73.10 x 2=$146). We then multiplied this wage rate by the estimated annual burden hours to calculate a total annualized cost burden of $2,099,334 (rounded) ($146 x 14,379 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 2023. 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	14,379	$146/hour	$2,099,334

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 (eCopy). Submissions may be prepared using eSTAR and sent to FDA through the CDRH Portal (free) or mailed to FDA. As noted above in section 3 of this supporting statement, as of October 1, 2025, FDA will require that De Novo Request electronic submissions be provided as described in the guidance document "Electronic Submission Template for Medical Device De Novo Requests" (see eSTAR Program, https://www.fda.gov/medical-devices/how-study-and-market-your-device/estar-program).

If mailed, the least expensive type of eCopy media is a CD, approximately $0.25 per CD. We recommend respondents use priority shipping and assume average costs of $1.30 per mailed submission. Assuming mailed submissions represent 50 percent of De Novo submissions, we estimate operational costs of $65 annually (($0.25 + $1.30) x 42 submissions = $65.10; rounded).

14. Annualized Cost to the Federal Government

Based on an internal cost model, we assume a fully-loaded cost of $348,722 per position (full-time equivalent, or FTE). Multiplying that figure by 20 FTEs, we estimate an annual cost to the Federal government of $6,974,440 ($348,722 x 20 FTEs).

15. Explanation for Program Changes or Adjustments

We have provided the guidance document, "*Electronic Submission Template for Medical Device De Novo Requests*" with this request for approval. Given that all submissions were previously received electronically and the ability to voluntarily submit De Novo requests using eSTAR was included in the previous ICR, inclusion of the guidance in this ICR is not expected to impact the estimated burden.

Our estimated burden for the information collection reflects an overall increase of 2,002 hours and a corresponding increase of 11 responses. We attribute this adjustment to an increase in the number of submissions received annually.

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.