Reclassification Petitions for Medical Devices
OMB No. 0910-0138
21 CFR 860.123
SUPPORTING STATEMENT

Terms of Clearance: None.

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

The Food and Drug Administration (FDA) is requesting extension of approval from the Office of Management and Budget (OMB) for the information collection requirements in the following reclassification regulation 21 CFR 860.123.

This regulation requires device manufacturers to provide, in a petition for device reclassification, specification of the type of device, a statement of the action requested, and a justification for the request to reclassify.

The classification regulation, 21 CFR Part 860 including subpart C, reclassification, was promulgated under the authority of 21 U.S.C. 360(e) and (f), 360d(b), 360e(b), 360j(1), and 360i(b)(1)(A).

The 1976 amendments to the Food, Drug, and Cosmetic Act (the act) provide three tiers of regulatory control for medical devices, by establishing three classes of medical devices, and requiring that all devices be classified into one of these three. The classification of a device depends upon the degree of regulatory control necessary to provide a reasonable assurance of the safety and effectiveness of the device. The three tiers of regulatory control are: 1) Class I - general controls, subject to sections 501 adulteration, 502 misbranding, 510 registration, 516 banned devices, 518 notification and other remedies, 519 records and reports, and 520 general provisions of the act; 2) Class II - performance standards; and 3) Class III - premarket approval. The amendments also provide for changing device classification.

The Safe Medical Devices Act of 1990 and the 1992 amendments amended the definition of a Class II device. Under the 1990 amendments, Class II (now identified as special controls) devices are those devices for which there is insufficient information to show that the general controls alone will provide reasonable assurance of the safety and effectiveness of the device type, but for which there is sufficient information to establish special controls to provide such assurance, including the promulgation of performance standards.

In addition to the mandated classification of all device types offered legally for sale prior to the enactment of the amendments, post-amendments devices that are not substantially equivalent to a pre-amendments device are automatically placed in Class III by section 513(f) of the act. Preamendments device types that were

classified into class III are reviewed through the premarket notification (510(k)) process. FDA will call for Premarket Approval applications (PMAs) under section 515(b) of the Act for the preamendments Class III device types, unless they are reclassified. Preamendments device types that were regulated as new drugs by FDA (known as transitional devices), prior to the enactment of the amendments, were automatically placed into Class III and required PMA, by section 520(l) of the act. FDA may propose to reclassify a transitional device if it believes we have sufficient information to provide reasonable assurance of the safety and effectiveness of the device type with general or general and special controls. A manufacturer may also petition the agency to reclassify a transitional device type.

The reclassification procedures regulation requires a manufacturer to submit specific data when petitioning for reclassification. This includes both a "supplemental data sheet" (§ 860.123(a)(3)) (Form FDA 3427) and a "classification questionnaire" ((§ 860.123(a)(4)) (Form FDA 3429). Each of these forms contains a series of questions concerning the safety and effectiveness of the device type.

The act provides for any person to petition for reclassification of a device from any class to any other class. However, these provisions serve primarily as a vehicle for manufacturers to seek reclassification from a higher to a lower class, thereby reducing the regulatory burden placed on a particular device type. If approved, the reclassification petition provides an alternative route to market, i.e., 510(k), in lieu of PMA for Class II devices; most reclassification petitions are submitted seeking reclassification of Class III device types that currently require PMA, to avoid the need for PMA. Neither the act nor the regulations require that any device type be reclassified.

2. Purpose and Use of the Information Collection

The staff of the Center for Devices and Radiological Health (CDRH) is responsible for reviewing petitions for reclassification and determining whether the subject device will be reclassified. In some instances, FDA also submits such petitions to one of its medical device advisory panels for review and recommendations. FDA's decision regarding the reclassification of a device is based primarily upon the information contained in the petition.

3. Use of Improved Information Technology and Burden Reduction

A final rule was published in the Federal Register of March 20, 1997 (62 FR 13430) that would, under certain circumstances, permit the agency to accept electronic submissions. The intended effect of the rule is to permit the use of electronic technologies in a manner that is consistent with FDA's overall mission. Published in the same issue of the Federal Register (62 FR 13467), is a notice of the establishment of a public docket to provide information on submissions the agency is prepared to accept electronically. FDA's Center for Devices and Radiological Health has not identified reclassification petitions as a type of submission it is

prepared to accept electronically. Reclassification petitions must be addressed to the appropriate mailing address listed in § 860.123(b)(1) and must contain an original and two copies (§ 860.123(b)(4)). Section 860.123 does not specifically provide for the use of electronic submissions. Each petition is unique, containing information with supporting data to show why reclassification for the device type will provide reasonable assurance of the safety and effectiveness of the device type. The principal data in such a petition will typically be reports of clinical trials.

4. Efforts to Identify Duplication and Use of Similar Information

The Food and Drug Administration is the only federal agency responsible for premarket review of medical devices; as such, there is no duplication of effort.

Similar information to what is needed for reclassification of devices may exist in the PMA applications for some devices. If the PMA applicant is willing to make information from their PMA public, this information may also be used for purposes of reclassification. If, however, the applicant of the PMA is not willing to make their information public, FDA is precluded from using the data to assist reclassifying devices by sections 520(c) and (h) of the act. However, the agency can rely on all publicly available information, such as literature, to assist in reclassification decisions.

5. Impact on Small Businesses or Other Small Entities

Any individual or organization may submit reclassification petitions; the requirements are the same regardless of the organization's size. There are no user fees for reclassification petitions. FDA aids small businesses in dealing with the regulations by providing guidance and information through CDRH's Division of Small Manufacturers, International, and Consumer Assistance (DSMICA). DSMICA provides technical and non-financial assistance to firms through a comprehensive program including seminars, educational conferences, printed and electronic information materials, and via e-mail and a toll-free telephone number. Other CDRH staff members are also available to respond to questions at any time.

6. Consequences of Collecting the Information Less Frequently

If the information were collected less frequently, manufacturers would not be able to take advantage of the reclassification alternative provided in the act. Petitions for reclassification are submitted only when an organization or individual seeks reclassification; as discussed above, the law does not require FDA to reclassify devices, but does require that FDA review the reclassification petitions received.

There are no technical or legal obstacles to the collection of this information.

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

The information collection is consistent with 5 CFR 1320.5.

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

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the Federal Register of November 14, 2011 (76 FR 70460). No comments were received.

CDRH has continually maintained contact with industry. Informal communications concerning the importance and effect of reclassification are provided primarily through trade organizations, and via CDRH's website. The consensus from the Agency's most recent contact with these trade organizations is that they are in favor of the program. The trade organizations involved are AdvaMed, the Food and Drug Law Institute (FDLI), and the National Electrical Manufacturers Association (NEMA).

AdvaMed
Tara Federici
1030 15th Street, NW, Suite 1100
Washington, DC 20005
(202) 452-8240

Food and Drug Law Institute
1000 Vermont Avenue, NW
Suite 1200
Washington, DC 20005
(202) 371-1420

National Electrical Manufacturers Association (NEMA)
1300 North 17th Street
Suite 1847
Rosslyn, VA 22209
(703) 841-3200

CDRH has also conveyed that reclassification may save FDA resources.

9. Explanation of Any Payment or Gift to Respondents

No payment or gift is given to respondents.

10. Assurance of Confidentiality Provided to Respondents

No assurance of confidentiality is provided. Information provided to, or obtained by, FDA is subject to release under the Freedom of Information Act (5 U.S.C. 552) and the implementing regulations contained in 21 CFR Parts 20 and 21. Reclassification petitions are placed on public display, and FDA does not withhold any information. FDA advises petitioners not to include confidential information in their petitions.

11. Justification for Sensitive Questions

The information required does not include questions about sexual behavior, attitude, religious beliefs, or any other matters which are commonly considered private or sensitive in nature.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

FDA estimates the burden of this collection as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Activity	FDA Form Nos.	No. of Respondents	No. of Responses per Respondent	Average Burden per Response	Hours per Response	Total Hours
Supporting data for reclassification petition		6	1	6	497	2,982
Supplemental Data Sheet	3427	6	1	6	1.5	9
General Device Classification Questionnaire	3429	6	1	6	1.5	9
Total						3,000

Based on current trends, FDA anticipates that 6 petitions will be submitted each year. The time required to prepare and submit a reclassification petition, including the time needed to assemble supporting data and to prepare the forms, averages 500 hours per petition. This average is based upon estimates by FDA administrative and technical staff who are familiar with the requirements for submission of a reclassification petition, have consulted and advised manufacturers on these requirements, and have reviewed the documentation submitted.

12b. Annualized Cost Burden Estimate

The mean hourly wage for a life, physical and social scientist plus 40% for fringe benefits is $44.69 per hour which yields an estimated annual cost to respondents of $134,070. The hourly wage rate has been updated based on May 2010 Bureau of Labor and Statistics data for life, physical and social scientists (SOC Code Number 19-0000, http://www.bls.gov/oes/2010/may/oes_nat.htm#19-0000). This adjustment has caused a decrease of $80,640 to the annualized cost burden estimate.

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Life, physical and social scientist	3,000	$44.69	$134,070

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

There are no capital costs or operating maintenance costs associated with this collection of information.

14. Annualized Cost to the Federal Government

FDA estimates that it spends an average of six full time equivalents (FTEs) reviewing and processing reclassification petitions. An FTE is projected to cost FDA/CDRH $212,953, which consists of the employee's salary and overhead. The burden imposed upon the government for this information collection is $1,277,718 per year. The FTE rate has been updated to the FY 2012 rate. This adjustment has caused an increase of $305,718 to the estimated annualized cost to the Federal government.

15. Explanation for Program Changes or Adjustments

There are no changes in burden hour estimate from the previous information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

The results of reclassification of medical device actions will not be published for statistical use. Under § 860.125, when the Commissioner refers a reclassification petition to a classification panel for its recommendation or consults with a panel concerning a reclassification petition, the Commissioner will distribute a copy of the petition, or its relevant portions, to each panel member. Under § 860.130(d), the rulemaking procedures in § 10.40 apply to proceedings to reclassify a device. A regulation proposed by an interested person in a petition may be published in the Federal Register (see § 10.40(a)(4) and (b)(1)(vii)).

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

FDA is not seeking approval to not display the expiration date of OMB approval.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.