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

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 Section 860.123.

21 CFR 860.123 - Reporting

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 assignment of a device into a class depends upon the degree of regulatory control necessary to provide a reasonable assurance of the safety and effectiveness of the device. The amendments also provide for changing device classification. 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 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 by themselves will provide reasonable assurance of the safety and effectiveness of the device type, but 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. Preamendment 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 preamendment 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 the submission of specific data when a manufacturer is petitioning for reclassification. This includes a "supplemental data sheet" (Form 3427) and a "classification questionnaire" (Form 3429). Each of these is 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. These provisions, however, 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. The reclassification petition, if approved, provides a different route, i.e., 510(k), to the market in lieu of PMA for Class III type devices; most reclassification petitions are submitted seeking reclassification of Class III device types that 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

The staff of the Center for Devices and Radiological Health (CDRH) is responsible for reviewing petitions for reclassification and determining whether or not the subject device will be reclassified. In some instances the FDA also submits the petition(s) to one of its medical device advisory panels for review and recommendations. The decision of whether or not to reclassify a device is primarily based upon the information contained in the petition.

3. Use of Information Technology and Burden Reduction

A final rule was published in the FEDERAL REGISTER of March 20, 1997 (62 FR 13429) that would, under certain circumstances, permit the agency to accept electronic submissions. The intended effect of this proposal is to permit the use of electronic technologies in a manner that is consistent with FDA's overall mission. For reclassification petitions, an electronic copy of the paper copy may be submitted as one copy of the petition to reduce burden. 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. FDA/CDRH is researching the use of electronic submissions and reclassification petitions, and presently has guidance on their internet web site regarding electronic copies of submissions.

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 FDA's PMA application 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.

5. Impact on Small Business or Other Small Entities

Any individual or organization may submit reclassification petitions; the requirements are the same regardless of the firm size. FDA aids small businesses in dealing with the regulation by providing guidance and information through the Division of Small Manufacturers, International, and Consumer Assistance (DSMICA) of CDRH. This office provides technical and non-financial assistance to firms, through a comprehensive program including seminars 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 at any time. There are no user fees for reclassification petitions.

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 a firm seeks reclassification; as discussed above, the law does not require FDA to reclassify devices, but does require that we 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 Agency

In the Federal Register of December 4, 2008 (73 FR 73938), FDA solicited comments on this information collection. There were no comments on the information collection.

The CDRH has continually maintained contact with industry. Informal discussions relating to the importance and effect of reclassification is communicated primarily through trade organizations. The consensus of our most recent contact with the organizations is that they have are in favor of the program. The Center has also conveyed that reclassification may save FDA resources. The trade Organizations involved are AdvaMed, the Food and Drug Law Institute (FDLI), and the National Electrical Manufacturers Association (NEMA).

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

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

9. Explanation of Any Payment of Gift to Respondents

No payment or gift is given to respondents.

10. Assurance of Confidentiality Provided to Respondent

Data relating to this information collection is subject to release under 21 CFR Part 20, "Public Information," in determining whether documents may be disclosed under Freedom of Information. Reclassification petitions are placed on public display, and FDA does not withhold any information. FDA advises petitioners not to include confidential information in the petition.

11. Justification 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. Estimate of Hour Burden Including Annualized Hourly Costs

FDA estimates the burden of this collection as follows

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	FDA Form Nos.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
860.123	3427 and 3429	6	1	6	500	3,000

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

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, 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

Cost to respondents

The mean hourly rate for an employee a life, physical and social scientist plus fringe benefits is $71.57 per hour which yields an estimated annual cost to respondents of $214,710.

13. Estimate of the Other Total Annual Cost Burden to Respondent of Recordkeepers

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 average full time equivalent employee is projected to cost FDA/CDRH $162,000, which consists of the employee's salary and any overhead which accompany that employee. The burden imposed upon the government for this information collection is $972,000 per year,

15. Explanation of Program Changes of Adjustment

There are no changes in burden 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.

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

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

18. Exceptions to Certification for Paperwork Reduction Act Submissions

No exception is sought to the certification statement identified in Item 19 of OMB Form 83-I.

B. Collection of Information Employing Statistical Methods

There are no statistical methods being employed in this collection of information.

LIST OF ATTACHMENTS
for
RECLASSIFICATION PETITONS SUPPORTING STATEMENT:

1. Reclassification regulation 21 CFR Section 860.12321 U.S.C. 360c(e) and (f), 360d(b), 360e(b), 360j(l) and 360I(b)(1)(A)
2. The Safe Medical Devices Act of 1990 and the Medical Devices Amendments of 1992
3. Supplemental Data Sheet (Form 3427)
4. Classification Questionnaire (Form 3429)
5. 60 Day Federal Register Notice