SUPPORTING STATEMENT
PREMARKET NOTIFICATION
21 CFR PART 807, SUBPART E
OMB NO. 0910-0120

A. JUSTIFICATION

Section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act) and the implementing regulation 21 CFR 807 Subpart E, require a person who intends to market a medical device to submit a premarket notification submission to the Food and Drug Administration at least 90 days before proposing to begin the introduction, or delivery for introduction into interstate commerce, for commercial distribution of a device intended for human use. Based on the information provided in the notification, FDA must determine whether the new device is substantially equivalent to a legally marketed device, as defined in 21 CFR 807.92(a)(3). If the device is determined to be not substantially equivalent to a legally marketed device, it must have an approved premarket approval application (PMA), Product Development Protocol or be reclassified into Class I or Class II before being marketed. The FDA makes the final decision of whether a device is equivalent or not equivalent.

The Medical Device User Fee and Modernization Act of 2002 (MDUFMA), P.L. 107-250), added section 510(o) to the Federal Food, Drug, and Cosmetic Act (the act) to establish regulatory requirements for reprocessed single-use devices (SUDs) (MDUFMA section 302(b), the act section 510(o)). MDUFMA was signed into law on October 26, 2002. Section 301(b) of MDUFMA added requirements for reprocessed SUDs to section 510 of the act.

1. Circumstances Making the Collection of Information Necessary

The Food and Drug Administration (FDA) is requesting approval for the information collection requirements contained within 21 CFR 807 Subpart E. These requirements are:

21 CFR 807.81 - Reporting

States when a premarket notification is required.

21 CFR 807.87 - Reporting

Specifies information required in a premarket notification submission.

21 CFR 807.92 – Reporting

Specifies information required in a premarket notification summary

21 CFR 807.93 – Reporting

Specifies content and format of a 510 (K) statement.

FDA is also requesting OMB approval for the following forms:

Form FDA 3654 " Standard Data Reports for 510 (K)s

Form FDA 3541 " Premarket Notification [510 (K)] Status

Form FDA 3514 " CDRH Premarket Review Submision Cover Sheet

A premarket notification is required to be submitted by a person who is:

Introducing a device to the market for the first time;
Introducing or reintroducing a device which is significantly changed or modified in design, components, method of manufacturer, or the intended use that could affect the safety and effectiveness of the device.

Section 510(k) of the FD&C Act allows for exemptions to the 510(k) submissions, i.e., a premarket notification would not be required if the FDA determines that premarket notification is not necessary for the protection of the public health, and these are specifically exempted through the regulatory process. Under 21 CFR 807.85, "Exemption from premarket notification", a device is exempt from premarket notification if the device intended for introduction into commercial distribution is not generally available in finished form for purchase and is not offered through labeling or advertising by the manufacturer, importer, or distributor for commercial distribution, and the device meets one of the following conditions:

(1) It is intended for use by a patient named in order of the physician or dentist (or other specially qualified persons); or
(2) It is intended solely for use by a physician or dentist and is not generally available to other physicians or dentists.

A commercial distributor who places a device into commercial distribution for the first time under their own name and a repackager who places their own name on a device and does not change any other labeling or otherwise affect the device, shall be exempted from premarket notification if:

(1) The device was legally in commercial distribution before May 28, 1976; or
(2) A premarket notification was submitted by another person.

Additionally, the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Attachment 4) provided the authority for statutory exemption from the premarket notification requirements of the act in section 510(l) and 510(m). Section 510(l) states that a 510(k) is not required for any class I device with the exception of those that are intended for a use which is of substantial importance in preventing impairment of human health, or presents a potential unreasonable risk of illness or injury. Section 510(m) states that a class II device may be exempted from the 510(k) requirements of that act if a 510(k) is not necessary to provide reasonable assurance of safety and effectiveness.

21 CFR Section 807.87 on premarket notification lists the information required in each submission. Each premarket notification submission shall contain the following information:

(a) The device name, including both the trade or proprietary name and the common or usual name or classification name of the device.
(b) The establishment registration number, if applicable, of the owner or operator submitting the premarket notification submission.
(c) The class in which the device has been put under section 513 of the Act and, if known, its appropriate panel; or if the owner or operator determines that the device has not been classified

under such section, a statement of the determination and the basis for the person's determination that the device is not so classified.

(d) Action taken by the person required to comply with the requirements of the Act under section 514 for performance standards.

(e) Proposed labels, labeling, and advertisements sufficient to describe the device, it's intended use, and the directions for its use. Where applicable, photographs or engineering drawings should be supplied.

(f) A statement indicating that the device is similar to and/or different from other products of a comparable type in commercial distribution, accompanied by data to support the statement. This information may include an identification of similar products, materials, design considerations, energy expected to be used or delivered by the device, and a description of the operational principles of the device.

(g) Where a person required to register intends to introduce into commercial distribution a device that has undergone a significant change or modification that could significantly affect the safety or effectiveness of the device, or the device is to be marketed for a new or different indication for use, the premarket notification submission must include appropriate supporting data to show that the manufacturer has considered what consequences and effects that change or modification or new use might have on the safety and effectiveness of the device.

(h) A 510(k) summary as described in §807.92 or a 510(k) statement as described in §807.93.

(i) A financial certification or disclosure statement or both, as required by part 54 of 21 Code of Federal Regulations.

(j) For submissions claiming substantial equivalence to a device which has been classified into class III under section 513(b) of the act:

(i) Which was introduced or delivered for introduction into interstate commerce for commercial distribution before December 1, 1990 and

(ii) For which no final regulation requiring premarket approval has been issued under section 515(b) of the act, a summary of the types of safety and effectiveness problems associated with the type of devices being compared and a citation to the information upon which the summary is based (class III summary). The 510(k) submitter shall also certify that a reasonable search of all information known or otherwise available about class III device and other similar legally marketed devices has been conducted (class III certification), as described in 807.94. This information does not refer to information that already has been submitted to the Food and Drug Administration (FDA) under Section 519 of the act. FDA may require the submission of the adverse safety and effectiveness data described in the class III summary or citation.

(k)A statement that the submitter believes, to the best of his or her knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

(l) Any additional information regarding the device requested by the Commissioner that is necessary for the Commissioner to make a finding as to whether or not the device is substantially equivalent to a device in commercial distribution. A request for additional information will advise the owner or operator that there is insufficient information contained in the original premarket notification submission for the Commissioner to make this determination and that the owner or operator may either submit the requested data or a new premarket notification containing the requested information at least 90 days before the owner or operator intends to market the device or submit a premarket approval application in accordance with section 515 of the Act. If additional information is not submitted within 30 days following the date of the request, the Commissioner will consider the premarket notification to be withdrawn.

MDUFMA added section 510(o) to the Federal Food, Drug, and Cosmetic Act (the act) to establish new

regulatory requirements for reprocessed single-use devices (SUDs). Section 510(o) of the act requires that FDA review the types of reprocessed SUDs subject to premarket notification requirements and identify which of these devices require the submission of validation data to ensure their substantial equivalence to predicate devices. Section 510(o) also requires that FDA review critical and semi-critical reprocessed SUDs that are currently exempt from premarket notification requirements and determine which of these devices require the submission of premarket notifications to ensure their substantial equivalence to predicate devices.

FDA has identified the reprocessed SUDs that require the submission of validation data to date. The requirement to submit validation data for certain reprocessed single-use devices has largely been incorporated into the premarket notification program. As with all other devices, new premarket notifications for reprocessed SUDs will be required as new manufacturers enter the market or manufacturers with cleared premarket notifications make significant changes to their device. The burden estimates below include the burden for submitting premarket notifications for reprocessed SUDs with the burden for all other devices. FDA may amend the lists of reprocessed SUDs that require the submission of premarket notifications with validation data as necessary.

2. Purpose and Use of the Information

The information collected in a premarket notification is used by the medical, scientific, and engineering staffs of FDA in making substantial equivalence determinations as to whether or not devices can be allowed to enter the U.S. market. If the information were not collected, the impact to the Federal program would be negligible. The impact, however, to the public health of the U.S. would be great. The premarket notification review process allows for scientific and/or medical review of devices, subject to 510(k) of the Act, to confirm that the new devices are as safe and as effective as legally marketed predicate devices. This review process, therefore, prevents potentially unsafe and/or ineffective devices, including those with fraudulent claims, from entering the U.S. market.

3. Use of Information Technology and Burden Reduction

In the **Federal Register** of March 20, 1997, FDA published a final rule establishing procedures for electronic records, electronic signatures, and electronic submissions. A sponsor, applicant or manufacturer may use the appropriate technology in accordance with this rule to comply with the requirements of the guidance.

There are no technical or legal obstacles to the collection of this information. The Center for Devices and Radiological Health (CDRH) has carefully studied the subject of electronic submittals of Premarket Notifications (510(k)s), and has concluded that electronic submittals would be helpful to the review process.

CDRH is accepting medical device applications in electronic form. The Office of Device Evaluation (ODE) and the Office of In Vitro Diagnostic Device Evaluation and Safety are currently developing formal guidelines regarding electronic submissions. Submission of electronic documents rather than paper will be voluntary on the part of manufacturers, and will also meet the requirements of Government Paper Elimination Act (GPEA) Reviewers will have ready access to the electronic submission for reading and review on their desktop computers. Reviewer notes will also be stored electronically directly, without the need to scan paper documents. In the interim, FDA has provided some informal guidance on electronic submissions, entitled “Electronic Copies for Premarket Submissions.” Until these electronic submissions

are finalized, CDRH is requesting that industry give prior notification of their desire to submit an application in electronic form. This lead time is important in order to assure that the reviewer has the necessary hardware and software to review the electronic application so that the electronic submission will facilitate the review process.

It should be understood that an electronic application does not change the order in which submissions are reviewed. No preferential treatment will be given to manufacturers who submit an electronic application. In addition, at least one paper copy of the submission is also required. Additional copies of some reports may be requested in order to help facilitate the review.

4. Efforts to Identify Duplication and Use of Similar Information

FDA is the only agency responsible for the collection of this information, and there are no requirements for the submission of similar information. Therefore, no duplication of data exists. No data exists from any source, other than the premarket notification submitter, that can be used to provide FDA with information regarding safety and effectiveness of devices subject to this regulation. No other data can be used to monitor the introduction of the devices subject to Section 510(k) of the Act.

With regard to reprocessors, this information would not be available to FDA if reprocessors did not submit it in premarket notifications.

5. Impact on Small Businesses or Other Small Entities

The information collection will have a minimal impact on a substantial number of small entities. FDA also aids small business in dealing with the requirements of the regulations by providing guidance and information through the Division of Small Manufacturers, International, and Consumer Assistance (DSMICA), and through the scientific and administrative staff, workshops in which FDA Staff participate, and through the CDRH website at http://www.fda.gov/cdrh . These efforts help to assure that the burden on all manufacturers, including small manufacturers, is minimized.

6. Consequences of Collecting the Information Less Frequently

Data relative to 510(k) premarket notification cannot be collected less frequently. The 1976 Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act require that notification be submitted at least 90 days before a device intended for human use is introduced into commerce. Ensuring compliance with the Act would not be possible if data were collected less frequently.

The information collected in the premarket notification is necessary for FDA to ensure that only those submissions for devices that are as safe and effective as legally marketed predicate devices are cleared for marketing.

A premarket notification [510(k)] is a premarketing application submitted to FDA to demonstrate substantial equivalence to a legally marketed device currently on the U.S. market, which does not require premarket approval. The consequence of not obtaining this information would be that the FDA would not be able to provide a mechanism for clearing devices for market.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.6

This information collection is consistent with the guidelines prescribed in 5 CFR 1320.6.

8. Efforts to Consult Outside Agency

In a **Federal Register** of February 28,2007, [72 FR 9005], the FDA published a 30 day notice soliciting comments on the information collection requirements. In response to that notice, no comments were received.

The premarket notification program is constantly involved in on-going discussions, video conferences, and training with groups outside the agency including the following:

AdvaMed
1200 G Street, NW
Suite 400
Washington, DC 20005
(202) 434-7228
Contact: Ms. Janet Trunzo, Executive Vice President, Technology and Regulatory Affairs

Food and Drug Law Institute (FDLI)
1000 Vermont Avenue, N.W.
Suite 200
Washington, DC 20005
(202) 371-1420
Contact: Mr. James J. Kelly, President and CEO

National Electrical Manufacturers Association (NEMA)
1300 North 17th Street
Suite 1847
Rosslyn, VA 22209
(703) 841-3200
Contact: Mr. Evan Gaddis

Medical Device Manufacturers Association (MDMA)
1900 K. Street, NW
Suite 300
Washington, D.C. 20006
(202) 349-7174
Contact: Mark Leahey, Esq.

FDA has issued many guidance documents to assist manufacturers in preparing premarket notification submissions including many guidances that address preparing premarket notifications for specific types of devices. Under 21 CFR 10.115, FDA issues these guidances as drafts and invites comments when the guidance sets forth an initial interpretation of a statutory or regulatory requirement or when it includes changes that are of more than a minor nature. In addition, in section 10.115, FDA invites interested

persons to submit comments at any time on an existing guidance, to suggest areas for guidance development, or to submit a draft guidance document to FDA for consideration. Following these procedures, FDA has used public input to review and revise existing guidance documents and to issue new guidance documents. The submitter of a premarket notification may choose an alternative to the recommendations of a guidance. FDA works with submitters to develop an alternative approach when appropriate.

Also, due to the premarket notification program's regulatory nature, FDA is constantly in contact with the respondents during the review of their submissions.

9. Explanation of Any Payment or Gift to Respondents

No payment or gifts in any manner or form shall be provided to respondents under this regulation.

10. Assurance of Confidentiality Provided to Respondent

Confidentiality of information submitted to FDA under a premarket notification is governed by the provisions of 21 CFR 807.95, and is mandated. However, the purpose of the 510(k) summaries or 510(k) statements submitted in a premarket notification is to make information available to the public within 30 days once a device has been cleared for marketing. These provisions do not permit disclosure of information in a premarket notification submission that is trade secret or commercial confidential unless that information has been previously disclosed or as permitted under the Federal Freedom of Information Act. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. Information provided under this collection is handled in a manner to comply with the FDA regulations on public information in 21 CFR Part 20 (Attachment 6).

11. Justification for Sensitive Questions

This information collection does not include questions pertaining to sexual behavior, attitude, religious beliefs, or any other matters that are commonly considered private or sensitive in nature.

12. Estimates of Hour Burden Including Annualized Hourly Costs

Approximately 79 hours is required to complete a 510(k) package (exclusive of preparing clinical data, research, etc.) The average to industry per hour for this type of work is $100. Therefore, FDA estimates the total reporting cost to industry for 510(k) submissions at $7,900 per submission. The estimated submission cost of $7,900 multiplied by 3,700 submissions per year equals $29,230,000.

The estimated total numbers of 510(k)s which are distributed by firms, as required when they choose to provide a 510(k) statement under 21 CFR 807.93, annually is 20,000. Approximately 30 minutes are needed to process a request for information, so the total annual hours expended is 10,000. An average salary for respondents is $25 per hour; therefore, the total number of hours (10,000) multiplied by the average salary ($25) equals $250,000. The total cost for the reporting burden is therefore estimated to be $29,480,000.

FDA has created FDA Form 3514 (Attachment 7), a summary cover sheet form to assist respondents in categorizing 510(k) information for submission to FDA. This form also assists respondents in categorizing information for other FDA medical device programs premarket approval applications (OMB No. 0910-0231), investigational device exemptions (OMB No. 0910-0078) and humanitarian device

exemptions (OMB No. 0910-0332). The total burden (978 hours) for FDA Form 3514 has been included in this information collection. A reference in each of the OMB Information Collections mentioned above will indicate that the overall burden for this form has been recognized in this collection (OMB 0910-0120).

FDA has created FDA Form 3541 (Attachment 8) to assist 510(k) submitters in requesting information on the status of the review of their 510(k) submission. Based on a review of the number of status requests in the past two years, FDA estimates that it will receive about 400 status requests in a year. The respondent must complete some basic identifying information about the 510(k) and then fax or mail it to FDA. FDA estimates that completing the form and mailing it to FDA will take about 15 minutes.

Section 204 of FDAMA amended section 514 of the act) (21 U.S.C. 360d). Amended section 514 allows FDA to recognize consensus standards developed by international and national organizations for use in satisfying portions of device premarket review submissions including premarket notifications or other requirements. FDA has published and updated the list of recognized standards regularly since enactment of FDAMA and has allowed 510(k) submitters to certify conformance to recognized standards to meet the requirements of § 807.87. Certification of conformance to a recognized standard may allow a manufacturer to submit an abbreviated 510(k). FDA has created FDA Form 3654 (Attachment 9) to standardize certification of conformance to a recognized standard. FDA believes that use of this form will simplify the certification process for 510(k) submitters and the review process for FDA. Based on a review of 510(k) notifications submitted in the last two fiscal years, FDA estimates that it will receive about 150 submissions with Form 3564.

Any person/manufacturer who proposes to begin commercial distribution of a device, intended for human use, into interstate commerce is required to send a premarket notification submission to the FDA at least 90 days in advance of marketing. Based on trends experienced in the past three (3) years, an estimated 3,700 submissions are expected each year. FDA's administrative and technical staff, who are familiar with the requirements for submission of premarket notifications, estimate that an average of 80 hours are required to prepare a submission. There is a variance in the preparation of the premarket notification submission because of the vast and varying complexities of medical devices. This includes preparation and writing of the notification, typing, and responding to any requests from FDA for supplemental information. FDA, therefore, estimates that a total of 303,528 hours of effort for reporting are required for the 3,700 anticipated submissions.

The estimate of burden for this collection of information is shown in the following tables:

Table 1.--Estimated Annual Reporting Burden [1]

21 CFR Section	Form Number	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
807 Subpart E		3,700	1 1	3,700 400	79	292,300
807.87	FDA Form 3514	1,956	1	1,956	0.5	978
807.90 (a)(3)	FDA Form 3541	400	1	400	0.25	100
807.87 (d) and (f)	FDA Form 3654	150	1	150	1	150
807.93		2,000	10	20,000	0.5	10,000
TOTALS						303,528

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

FDA has based these estimates on conversations with industry and trade association representatives, and from internal review of the documents listed in the tables above.

13. Estimate of Other Total Annual Cost Burden to Respondents or Recordkeepers

There are no additional costs associated with this information collection.

14. Annualized Cost to the Federal Government

FDA estimates that a total of 187 full time equivalent (FTE) positions consisting of a combination of medical officers, dental officers, scientific, and engineering professionals and support staff are required for premarket notification review and processing. Based on a cost of $107,000 per position (which is the agency's average cost of an FTE including their benefits), the estimated annual Federal cost is $20,009,000.

FTEs	Cost/FTE (incl Overhead)	Total Cost
187	$117,000	$21,879,000

15. Explanation for Program Changes or Adjustments

There was an adjustment made to correct an error in which 21 CFR 807.93 was incorrectly identified as a recordkeeping requirement but has been correctly changed to a reporting requirement. This adjustment did not result in a change in the original burden estimate. In addition, another adjustment has occurred for this collection of information. which in this case, has resulted in a reduction of burden hours.The number of 510(k) submissions has been decreasing each year, and is projected to decrease further in the future due to FDAMA, MDUFMA, product reclassification efforts, and CDRH reengineering and strategic efforts. The burden has changed due to the decrease in the number of submissions received from respondents, as more 510(k)-device exemptions have been granted. FDA now estimates that it will receive about 3,700 510(k) submissions per year. The total estimated burden hours for completion of a premarket notification have been therefore reduced The burden to this collection has decreased by 55,472 hours due to the reduction in the number of premarket notifications expected in a year.

16. Plans for Tabulation and Publication and Project Time Schedule

FDA does not intend to publish or tabulate the results of this information collection.

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

FDA is not requesting an exemption for display of the OMB expiration date.

18. Exception to Certification for Paperwork Reduction Act Submissions

FDA is not requesting an exemption to Certification for the Paperwork Reduction Act Submissions.

B. Collection of Information Employing Statistical Methods

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