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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0804]

Agency Information Collection Activities; Proposed Collection; Comment Request;

Premarket Notification

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on medical device premarket notification.

DATES: Submit either electronic or written comments on the collection of information by **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged.

Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2013-N-0804 for “Agency Information Collection Activities; Proposed Collection; Comment Request; Premarket Notification.” Received comments will be placed in the docket and, except for those

submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at:

<http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the

prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Premarket Notification--21 CFR Part 807, Subpart E

OMB Control Number 0910-0120--Extension

Section 510(k) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360(k)) and the implementing regulation under part 807 (21 CFR part 807, subpart E) requires a person who intends to market a medical device to submit a premarket notification submission to FDA 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 § 807.92(a)(3) (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, humanitarian device exemption (HDE), petition for Evaluation of Automatic Class III Designation (de novo), or be reclassified into class I or class II before being marketed. FDA makes the final decision of whether a device is substantially equivalent or not equivalent.

Section 807.81 states when a premarket notification is required. A premarket notification is required to be submitted by a person who is: (1) Introducing a device to the market for the first time; (2) introducing a device into commercial distribution for the first time by a person who is required to register; and (3) 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.

Form FDA 3514, a summary cover sheet form, assists respondents in categorizing administrative 510(k) information for submission to FDA. This form also assists respondents in categorizing information for other FDA medical device programs such as PMAs, investigational

device exemptions, and HDEs. Under § 807.87(h), each 510(k) submitter must include in the 510(k) either a summary of the information in the 510(k) as required by § 807.92 (510(k) summary) or a statement certifying that the submitter will make available upon request the information in the 510(k) with certain exceptions as per § 807.93 (510(k) statement). If the 510(k) submitter includes a 510(k) statement in the 510(k) submission, § 807.93 requires that the official correspondent of the firm make available within 30 days of a request all information included in the submitted premarket notification on safety and effectiveness. This information will be provided to any person within 30 days of a request if the device described in the 510(k) submission is determined to be substantially equivalent. The information provided will be a duplicate of the 510(k) submission including any safety and effectiveness information, but excluding all patient identifiers and trade secret and commercial confidential information.

Section 204 of the Food and Drug Administration Modernization Act (FDAMA) (Pub. L. 105-115) amended section 514 of the FD&C 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. Form FDA 3654, the 510(k) Standards Data Form, standardizes the format for submitting information on consensus standards that a 510(k) submitter chooses to use as a portion of their premarket notification submission (Form FDA 3654 is not for declarations of conformance to a recognized standard). FDA believes that use of this form will simplify the 510(k) preparation and review process for 510(k).

Under § 807.90, submitters may request information on their 510(k) review status 90 days after the initial login date of the 510(k). Thereafter, the submitter may request status reports every 30 days following the initial status request. To obtain a 510(k) status report, the submitter should complete the status request form, Form FDA 3541, and fax it to the Center for Devices and Radiological Health office identified on the form.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

Activity and 21 CFR Part/Section	Form No.	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
510(k) submission (807 subpart E)		3,900	1	3,900	79	308,100
Summary cover sheet (807.87)	FDA 3514	1,956	1	1,956	0.5 (30 minutes)	978
Status request (807.90(a)(3))	FDA 3541	218	1	218	0.25 (15 minutes)	55
Standards (807.87(d) and (f))	FDA 3654	2,700	1	2,700	10	27,000
510(k) statement (807.93)		225	10	2,250	10	22,500
Total						358,633

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

Dated: November 15, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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