estimates it will take half the time per response (30 hours).

In the **Federal Register** of June 13, 2019 (84 FR 27638), FDA published a 60-day notice requesting public comment on the proposed collection of information. Although one comment was received, it was not responsive to the four collection of information topics solicited.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Numbers of respondents	Numbers of responses per respondent	Total annual responses	Average burden per response	Total hours	Total capital costs
Submission of Initial rotational plans for health warning statements	4	1	4	60	240	$48
Supplement to approved plan	10	1	10	30	300	120
Total					540	168

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

FDA estimates a total of 4 respondents will submit a new original warning plan and take 60 hours to complete a rotational warning plan for a total of 240 burden hours. In addition, 10 respondents will submit a supplement to an approved warning plan at 30 hours per response for a total of 300 hours. The total burden for this collection is estimated to be 540 hours.

Capital costs are based on 14 respondents mailing in their submission at a postage rate of $12 for a 5-pound parcel (business parcel post mail delivered from the furthest delivery zone). Therefore, FDA estimates that the total postage cost for mailing the rotational warning plans to FDA to be $168.

We have adjusted our burden estimate, which has resulted in a decrease of 5,460 hours and 86 respondents to the currently approved burden. We received a total number of 44 original smokeless warning plans, and a total of 17 supplements. After receiving the initial influx of original warnings plans, FDA does not expect to receive as many original warning plans annually. We expect that a few supplements will continue to be received as new products are marketed or as warning plans are revised. We anticipate a total number of 10 supplements submitted annually and 4 original smokeless warning plans.

Dated: October 17, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–23250 Filed 10–24–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–2686]

Medical Devices; Exemptions From Premarket Notification: Class II Devices; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing its intent to exempt a list of class II devices from premarket notification requirements, subject to certain limitations. The Agency has determined that, based on established factors, these devices no longer require premarket notification to provide reasonable assurance of safety and effectiveness. FDA is publishing this notice to obtain comments regarding the proposed exemptions, in accordance with the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: Submit either electronic or written comments on the notice by December 24, 2019.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before December 24, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 24, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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–2019–N–2686 for ''Medical Devices; Exemptions from Premarket Notification: Class II Devices; Request for Comments.'' Received comments, those filed in a timely manner (see

ADDRESSES), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff 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 Dockets Management Staff. 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: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Jismi Johnson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1524, Silver Spring, MD 20993, 301–796–6424, *jismi.johnson@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Statutory Background

Section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and the implementing regulations, 21 CFR part 807 subpart E, require persons who intend to market a new device to submit and obtain clearance of a premarket notification (510(k)) containing information that allows FDA to determine whether the new device is ''substantially equivalent'' within the meaning of section 513(i) of the FD&C Act to a legally marketed device that does not require premarket approval.

The 21st Century Cures Act (Cures Act) (Pub. L. 114–255) was signed into law on December 13, 2016. Section 3054 of the Cures Act amended section 510(m) of the FD&C Act. As amended, section 510(m)(1)(A) of the FD&C Act requires FDA to publish in the **Federal Register** a notice containing a list of each type of class II device that FDA determines no longer requires a report under section 510(k) of the FD&C Act to provide reasonable assurance of safety and effectiveness. FDA is required to publish this notice within 90 days of the date of enactment of the Cures Act and at least once every 5 years thereafter, as FDA determines appropriate. Additionally, FDA must provide at least a 60-day comment period for any such notice required to be published under section 510(m)(1)(A) of the FD&C Act. FDA published this notice in the **Federal Register** of March 14, 2017 (82 FR 13609). Under section 510(m)(1)(B) of the FD&C Act, FDA must publish in the **Federal Register**, within 210 days of enactment of the Cures Act, a list representing its final determination regarding the exemption of the devices that were contained in the list published under section 510(m)(1)(A). FDA published that list in the **Federal Register** of July 11, 2017 (82 FR 31976).

As amended, section 510(m)(2) of the FD&C Act provides that, 1 day after the date of publication of the final list under section 510(m)(1), FDA may exempt a class II device from the requirement to submit a report under section 510(k) of the FD&C Act upon its own initiative or a petition of an interested person, if FDA determines that a report under section 510(k) is not necessary to assure the safety and effectiveness of the device. To do so, FDA must publish in the **Federal Register** a notice of its intent to exempt the device, or of the petition, and provide a 60-day period for public comment. Within 120 days after the issuance of this notice, FDA must publish an order in the **Federal Register** that sets forth its final determination regarding the exemption of the device that was the subject of the notice. If FDA fails to respond to a petition under section 510(m)(2) of the FD&C Act within 180 days of receiving it, the petition shall be deemed granted. FDA is proposing to exempt a list of class II devices from premarket notification requirements, subject to certain limitations, upon its own initiative.

II. Factors FDA May Consider for Exemption

There are a number of factors FDA may consider to determine whether a 510(k) is necessary to provide reasonable assurance of the safety and effectiveness of a class II device. These factors are discussed in the January 21, 1998, **Federal Register** notice (63 FR 3142) and subsequently in the guidance the Agency issued on February 19, 1998, entitled ''Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff'' (''Class II 510(k) Exemption Guidance'') (Ref. 1). Accordingly, FDA generally considers the following factors to determine whether premarket notification is necessary for class II devices: (1) The device does not have a significant history of false or misleading claims or of risks associated with inherent characteristics of the device; (2) characteristics of the device necessary for its safe and effective performance are well established; (3) changes in the device that could affect safety and effectiveness will either (a) be readily detectable by users by visual examination or other means such as routine testing, before causing harm, or (b) not materially increase the risk of injury, incorrect diagnosis, or ineffective treatment; and (4) any changes to the device would not be likely to result in a change in the device's classification. FDA may also consider that, even when exempting devices, these devices would still be subject to the limitations on exemptions.

III. Limitations on Exemptions

FDA has determined that premarket notification is not necessary to assure the safety and effectiveness of the class II devices listed in table 1. This determination is based, in part, on the Agency's knowledge of the device, including past experience and relevant reports or studies on device performance (as appropriate), the applicability of general and special controls, and the Agency's ability to limit an exemption.

A. General Limitations of Exemptions

FDA's proposal to grant an exemption from premarket notification for class II devices listed in table 1 applies only to those devices that have existing or reasonably foreseeable characteristics of commercially distributed devices within that generic type. FDA proposes that a manufacturer of a listed device would

still be required to submit a premarket notification to FDA before introducing a device or delivering it for introduction into commercial distribution when the device meets any of the conditions described in 21 CFR 884.9 to 21 CFR 890.9.

B. Partial Limitations of Exemptions

In addition to the general limitations, FDA may also partially limit an exemption from premarket notification requirements to specific devices within a listed device type when initial Agency assessment determines that the factors laid out in the Class II 510(k) Exemption Guidance (Ref. 1) do not weigh in favor of exemption for all devices in a particular group. In such situations where a partial exemption limitation has been identified, FDA has determined that premarket notification is necessary to provide a reasonable assurance of safety and effectiveness for these devices. In table 1, for example, FDA is listing the proposed exemption of the optical position/movement recording system but limits the exemption to such devices that are for prescription (Rx) use only. FDA believes that FDA review (*e.g.,* premarket notification) of an optical position/movement recording system for over-the-counter (OTC) use is necessary to ensure that the exercises and activities led by the system are appropriate for a user's rehabilitation and to assess the measurement accuracy of the system. Additionally, a therapeutic massager to internally massage trigger points in the pelvic floor musculature would exceed the exemption limitation and would require 510(k) review if it is indicated for OTC use, lacks a quantitative feedback mechanism, or lacks a disposable covering.

IV. List of Class II Devices

FDA is identifying the following list of class II devices that, if finalized, would no longer require premarket notification under section 510(k) of the FD&C Act, subject to the general limitations to the exemptions found in §§ 884.9 to 890.9:

TABLE 1—CLASS II DEVICES

21 CFR section	Device type	Product code	Partial exemption limitation (if applicable)
884.6120	Accessory, Assisted Reproduction	MQG	Exemption is limited to assisted reproduction laminar flow workstations.
884.6180	Media, Reproductive	MQL	Exemption is limited to phosphate-buffered saline used for washing, and short-term handling and manipulation of gametes and embryos; culture oil used as an overlay for culture media containing gametes and embryos; and water for assisted reproduction applications.
888.4505	Instruments Designed for Press-Fit Osteochondral implants.	QBO	
890.5360	System, Optical Position/Movement Recording (Interactive Rehabilitation Exercise Devices).	LXJ	Exemption is limited to prescription (Rx) use only.
890.5670	Massager, Therapeutic, to Internally Massage Trigger Points in the Pelvic Floor Musculature.	OSD	Exemption is limited to prescription (Rx) use only devices which incorporate a quantitative feedback mechanism and a disposable covering.

FDA will assign new product codes to the device types that will be exempt subject to the partial limitations in order to ensure that these devices can be separated from devices that do not fall within the partial exemption limitation under the existing product code (*i.e.,* exempt and non-exempt devices within a device type will have distinct product codes).

FDA is also revising the name of product code LXJ to further clarify the device type that this product code is intended to represent. The device type was previously ''System, Optical Position/Movement Recording.'' This product code also includes types of rehabilitation devices other than optical position/movement recording systems; therefore, to more accurately reflect the devices which fall within this device type (product code LXJ), the device type has been renamed ''Interactive Rehabilitation Exercise Devices.''

V. Reference

The following reference is on display in the Dockets Management Staff (see **ADDRESSES**) and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is also available electronically at *https://www.regulations.gov.* FDA has verified the website address, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. FDA Guidance, ''Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff,'' February 19, 1998, available at *https://www.fda.gov/media/72685/download.*

Dated: October 21, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–23308 Filed 10–24–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–1262]

Notice of Approval of Product Under Voucher: Rare Pediatric Disease Priority Review Voucher

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of approval of a product redeeming a priority review voucher. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Food and Drug Administration Safety and Innovation Act (FDASIA), authorizes FDA to award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA is required to publish notice of the issuance of vouchers as well as the approval of products redeeming a