4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-D-0967]

Intent to Exempt Certain Unclassified Medical Devices from Premarket Notification Requirements; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance "Intent to Exempt Certain Unclassified Medical Devices from Premarket Notification Requirements." This guidance describes FDA's intent to exempt certain unclassified medical devices from premarket notification requirements. At this time, and based on the information currently available to the Agency, FDA believes the devices identified in this guidance meet the standards for exemption from premarket notification. This guidance has been implemented without prior comment, but it remains subject to comment in accordance with the Agency's good guidance practices.

DATES: The announcement of the guidance is published in the *Federal Register* on **[INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time 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): 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-2014-D-0967 for "Intent to Exempt Certain Unclassified Medical Devices from Premarket Notification Requirements." 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 Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- 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.govinfo.gov/content/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, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document titled "Intent to Exempt Certain Unclassified Medical Devices from Premarket Notification Requirements" to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5441, Silver Spring, MD

20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Erica Takai, Center for Devices and Radiological Health, Food and Drug Administration, 301-796-6353.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance titled "Intent to Exempt Certain Unclassified Medical Devices from Premarket Notification Requirements."

In the commitment letter (section I.G of the Performance Goals and Procedures) that was drafted as part of the reauthorization process for the Medical Device User Fee Amendments of 2012, part of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112-144), FDA committed to proposing low-risk medical devices to exempt from premarket notification (510(k)) requirements. This guidance describes FDA's intent to exempt certain unclassified medical devices (that FDA intends to propose classifying into class I or II) from premarket notification requirements. At this time, FDA believes the devices being added to this guidance meet the standards for exemption from premarket notification requirements. Until such exemption occurs, or until FDA becomes aware of new information affecting its current understanding, FDA does not intend to enforce compliance with 510(k) requirements for these devices. Due to this enforcement policy, FDA does not expect manufacturers to submit 510(k)s for these devices during this time period.

This updated guidance supersedes the June 2019 guidance of the same title, "Intent to Exempt Certain Unclassified Medical Devices from Premarket Notification Requirements." The updated guidance includes five additional product codes that have been independently considered by panels and were recommended as appropriate for classification into class I or class II. FDA's current assessment is that these device types meet the standards for exemption from premarket notification. The five product codes included in the update to the guidance are: LDK-

Device, sensing, optical contour; MVV-Device, acupressure; MQZ-Prosthesis, nail; MIG-Strip, test isoniazid; and LXQ-Cup, eye.

This guidance is being implemented without prior public comment because the Agency has determined that prior public participation is not feasible or appropriate (see section 701(h)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(h)(1)(C)) and 21 CFR 10.115(g)(2)). FDA has determined that this guidance presents a less burdensome policy that is consistent with public health. Although this guidance is being implemented immediately without prior comment, it remains subject to comment in accordance with the Agency's good guidance practices(21 CFR 10.115(g)(3)(i)(D)). FDA will consider all comments received and revise the guidance as appropriate.

The guidance represents the current thinking of FDA on the intent to exempt certain unclassified medical devices from premarket notification requirements. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products. This guidance document is also available at https://www.regulations.gov, and https://www.fda.gov/regulatory-information/search-fda-guidance-documents, or https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics. Persons unable to download an electronic copy of "Intent to Exempt Certain Unclassified Medical Devices from Premarket Notification Requirements" may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the

document. Please use the document number GUI01300046 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521). The collections of information in the following table have been approved by OMB:

21 CFR Part; Guidance; or FDA Form	Topic	OMB Control No.
807, subpart E	Premarket notification	0910-0120

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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