4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-D-0025]

Medical Device Accessories--Describing Accessories and Classification Pathway for New Accessory Types; 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 entitled "Medical Device Accessories--Describing Accessories and Classification Pathways for New Accessory Types." This document provides guidance to industry and FDA staff about the regulation of accessories to medical devices. The guidance explains what devices FDA generally considers an "accessory" and encourages use of the de novo classification process under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to allow manufacturers and other parties to request risk- and regulatory control-based classification of accessories of a new type (i.e., accessories of a type that has not been previously classified under the FD&C Act, cleared for marketing under a 510(k) submission, or approved in an application for premarket approval (PMA)).

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

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-2015-D-0025 for "Medical Device Accessories--Describing Accessories and Classification Pathway for New

Accessory Types." 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.

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 guidance document entitled "Medical Device Accessories--Describing Accessories and Classification Pathway for New Accessory Types" to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5431, 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, 10903 New Hampshire Ave., Bldg. 66, rm. 5456, Silver Spring, MD 20993-0002, 301-796-6353 or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave,. Bldg. 71, rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA has jurisdiction over accessories because the definition of the term "device" provided in section 201(h) of the FD&C Act defines "device" to include, among other things, an "accessory." All accessories to articles that meet this definition of "device" are regulated under the FD&C Act.

This guidance is intended to provide guidance to industry and FDA staff about the regulation of accessories to medical devices. Accordingly, this guidance describes the types of

devices that FDA generally considers as accessories and discusses the risk- and regulatory control-based classification paradigm for these accessories. This information is expected to provide a greater level of transparency with regards to the classification of accessories and will aid FDA staff and industry in assuring that these devices are subject to an appropriate level of regulatory oversight by FDA. In addition, this guidance describes the use of the de novo classification process under section 513(f)(2) of the FD&C Act (21 U.S.C. 360c(f)(2)) for manufacturers to request risk- and regulatory control-based classifications of accessories of a new type that are low-moderate risk for which general controls or general and special controls provide a reasonable assurance of safety and effectiveness, but for which there is no legally marketed predicate device.

For the purposes of this guidance document, an "accessory" is defined as "a finished device that is intended to support, supplement, and/or augment the performance of one or more parent devices." It is important to note that FDA does not generally consider articles that do not meet the definition of an accessory as accessories simply because they may be used in conjunction with a device.

This guidance clarifies that classification of accessory devices, as for non-accessory devices, should reflect the risks of the device when used as intended and the level of regulatory controls necessary to provide a reasonable assurance of safety and effectiveness. Classifying an accessory in the same class as its parent device is appropriate when the accessory, when used as intended with the parent device, meets the criteria for placement in the class of the parent device. However, some accessories can have a lower risk profile than that of their parent device and, therefore, may warrant being regulated in a lower class.

In the Federal Register of January 20, 2015 (80 FR 2710), FDA published a notice of availability for the draft guidance entitled "Medical Device Accessories: Defining Accessories and Classification Pathway for New Accessory Types." FDA revised the guidance as appropriate in response to the comments. We received comments requesting that the scope of the guidance be expanded to apply to existing accessories that were previously classified. FDA is continuing to explore mechanisms for risk- and regulatory control-based reclassification of existing accessories. Therefore, the scope of the guidance has not been expanded and includes the use of the de novo classification process to classify accessories of a new type.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on the regulation of medical device accessories. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft 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 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm. Guidance documents are also available at https://www.regulations.gov. Persons unable to download an electronic copy of "Medical Device Accessories: Describing Accessories and Classification Pathway for New Accessory Types" may send an email request to CDRH-

Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 1770 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (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. The guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR parts 801 and 809 have been approved under OMB control number 0910-0485; the collections of information in 21 CFR part 807, subpart E have been approved under OMB control number 0910-0120; the collections of information in 21 CFR part 814 have been approved under OMB control number 0910-0231; the collections of information in 21 CFR part 860, subpart C have been approved under OMB control number 0910-0138; and the collection of information for new medical device accessories devices have been approved under OMB control number 0910-0823.

Dated: December 23, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-31669 Filed: 12/29/2016 8:45 am; Publication Date: 12/30/2016]