4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-D-2148]

Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled "Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices." This draft guidance provides a detailed description of the information that should be included in a premarket notification for a magnetic resonance diagnostic device (MRDD). This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment of this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: 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 Submit written requests for a single hard copy of the draft guidance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 entitled “Guidance for the Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices” 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.

Submit electronic comments on the draft guidance to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jana Delfino, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4236, Silver Spring, MD 20993-0002, 301-796-6503; or Sunder Rajan, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 62, rm. 1113, Silver Spring, MD 20993-0002, 301-796-4194.

SUPPLEMENTARY INFORMATION:

I. Background

The purpose of this document is to provide a detailed description of the information that should be included in a premarket notification for an MRDD. This document is an elaboration of the general requirements contained in 21 CFR 807.87 and is intended to be used in conjunction with general information regarding the content and format of a 510(k) premarket notification. The approach outlined in this guidance document is intended to facilitate the timely review and marketing clearance of MRDDs.

This draft guidance is applicable to MRDDs as defined in 21 CFR 892.1000. An MRDD is intended for general diagnostic use to present images that reflect the spatial distribution and/or magnetic resonance spectra that reflect frequency and distribution of nuclei exhibiting nuclear magnetic resonance. Other physical parameters derived from the images and/or spectra may also be produced. The device includes hydrogen-1 (proton) imaging, sodium-23 imaging, hydrogen-1 spectroscopy, phosphorus-31 spectroscopy, and chemical shift imaging (preserving simultaneous frequency and spatial information). MRDDs are class II medical devices that require premarket notification and an agency determination of substantial equivalence prior to marketing.

The principal components of current MRDDs include the main magnet, shim and gradient systems, radiofrequency transmitter and receiver, transmit and receive coils, power supplies, computer, and software. This draft guidance document is applicable to premarket notifications for new magnetic resonance imaging (MRI) and magnetic resonance spectroscopy systems, new components, and modifications to systems and components that have a significant impact on safety or effectiveness of the magnetic resonance diagnostic device. The information in this draft guidance document is also applicable to the MRI system components of dual-modality devices, such as positron emission tomography/MRI systems.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on "Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices." 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.

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 http://www.regulations.gov. Persons unable to download an electronic copy of "Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices" may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 340 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910-0120, and the collections of information in 21 CFR part 801 have been approved under OMB control number 0910-0485.

V. Comments

Interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be

seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

Dated: July 8, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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