



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; 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 "Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices." This guidance provides a detailed description of the information that should be included in a premarket notification for a magnetic resonance diagnostic device (MRDD).

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: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://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 <http://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-2148 for "Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices."

Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://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 <http://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 <http://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 "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.

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 guidance is to provide a detailed description of the information that should be included in a premarket notification for an MRDD. This guidance is a recommendation of how to comply with certain requirements contained in 21 CFR 807.87 and is intended to be used in conjunction with 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.

MRDDs are also electronic products under section 531(2) (21 U.S.C. 360hh(2)) of Subchapter C (Electronic Product Radiation Control (EPRC)) of the Federal Food, Drug and Cosmetic Act (FD&C Act). As such, MRDDs are subject to the radiological health requirements in Title 21, Subchapter J, parts 1000 through 1050 of the Code of Federal Regulations, including applicability of general and specific performance standards (parts 1010-1050) and other general requirements for reporting and recordkeeping (part 1002), notification and corrective actions for

defective or non-compliant electronic products (parts 1003 and 1004), and importation (part 1005).

This 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, patient supports, and physiological gating devices. This guidance document is applicable to premarket notifications for new magnetic resonance imaging (MRI) and magnetic resonance spectroscopy systems, components, and accessories, and modifications to systems, components, and accessories that could significantly affect the safety or effectiveness of the MRDD. The information in this guidance document is also applicable to the MRI system components of dual-modality devices, such as positron emission tomography/MRI systems.

In the Federal Register of July 14, 2015 (80 FR 41046), FDA announced the availability of the draft guidance and interested persons were invited to comment by October 13, 2015. FDA has considered the comments received, and has incorporated changes suggested by the comments, as appropriate.

This guidance supersedes FDA's guidance entitled "Guidance for Industry: Guidance for the Submissions of Premarket Notifications for Magnetic Resonance Diagnostic Devices" dated November 14, 1998.

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 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 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 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 (premarket notification), have been approved under OMB control number 0910-0120; the collections of information in 21 CFR part 801 (labeling) have been approved under OMB control number 0910-0485; the collections of information in parts 1002 through 1050 (electronic product requirements) have been approved under OMB control number 0910-0025; and the collections of information in the guidance document "Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff" have been approved under OMB control number 0910-0756.

Dated: November 15, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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