4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-D-5372]

Marketing Clearance of Diagnostic Ultrasound Systems and Transducers; 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 or Agency) is announcing the availability of a final guidance entitled "Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." This final guidance provides detailed recommendations for manufacturers seeking marketing clearance of diagnostic ultrasound systems and transducers, and includes guidance describing the types of modifications to a diagnostic ultrasound device for which FDA does not intend to enforce the requirement for a new premarket notification (510(k)).

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-2017-D-5372 for "Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." 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.

- 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.

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 guidance document entitled "Marketing Clearance of Diagnostic Ultrasound Systems and Transducers" 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: Shahram Vaezy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4227A, Silver Spring, MD 20993-0002, 301-796-6242; or Keith Wear, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 62, Rm. 2114, Silver Spring, MD 20993-0002, 301-796-2538.

SUPPLEMENTARY INFORMATION:

I. Background

This guidance provides detailed recommendations for manufacturers seeking marketing clearance of diagnostic ultrasound systems and transducers. This guidance supersedes FDA's guidance entitled "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers" dated September 9, 2008, regarding FDA's approach to the regulation of certain diagnostic ultrasound devices.

In addition to outlining regulatory approaches for certain diagnostic ultrasound devices, this guidance describes the types of modifications to a diagnostic ultrasound device for which FDA does not intend to enforce the requirement for a new 510(k). As before, manufacturers who

submit 510(k)s and receive marketing clearance will continue to be exempt from the Electronic Product Radiation Control reporting requirements in 21 CFR 1002.12, for diagnostic ultrasound devices, as described in the notice to industry entitled "Exemption from Reporting under 21 CFR 1002" dated February 24, 1986.[1]

FDA considered comments received on the draft guidance that appeared in the *Federal Register* of October 2, 2017 (82 FR 45856). FDA revised the guidance as appropriate in response to the comments.

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 information for manufacturers seeking marketing clearance of diagnostic ultrasound systems and transducers. 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. This guidance is not subject to Executive Order 12866.

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 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. Persons unable to download an electronic copy of "Marketing Clearance of Diagnostic Ultrasound Systems and Transducers" may send an email request to

[1] Available at https://www.fda.gov/downloads/RadiationEmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/UCM509874.pdf

CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 560 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information. 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 the following FDA regulations and guidance have been approved by OMB as listed in the following:

21 CFR Part or Guidance	Topic	OMB Control No.
807, subpart E	Premarket Notification	0910-0120
801	Medical Device Labeling Regulations	0910-0485
820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation	0910-0073
1002 and 1010	Reporting and Recordkeeping for Electronic Products - General Requirements	0910-0025
814, subpart A-E	Premarket Approval of Medical Devices	0910-0231
513(f)(2) FD&C Act	De Novo Classification Process (Evaluation of Automatic Class III Designation)	0910-0844
"Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff"	Q-submissions	0910-0756

Dated: June 21, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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