



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Marketing Clearance of Diagnostic Ultrasound Systems and Transducers; Draft Guidance for Industry and Food and Drug Administration Staff; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled "Marketing Clearance of Diagnostic Ultrasound Systems and Transducers; Draft Guidance for Industry and Food and Drug Administration Staff." This draft guidance provides detailed information recommended for manufacturers seeking marketing clearance of diagnostic ultrasound systems and transducers. This draft guidance is not final nor is it in effect at this time.

DATES: Submit either electronic or written comments on the draft guidance by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance 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; Draft Guidance for Industry and Food and Drug Administration Staff." 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 draft guidance document entitled "Marketing Clearance of Diagnostic Ultrasound Systems and Transducers; Draft Guidance for Industry and Food and Drug Administration Staff" 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. 2104, Silver Spring, MD 20993-0002, 301-796-2538.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

When finalized, this draft guidance will provide detailed recommendations for manufacturers seeking marketing clearance of diagnostic ultrasound systems and transducers. In addition, this draft guidance, when final, is intended to supersede FDA's 2008 guidance entitled, "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems

and Transducers," regarding FDA's approach to the regulation of certain diagnostic ultrasound devices. (Ref. 1). In addition to the regulatory approaches outlined in the 2008 document, additional guidance is provided for deciding when a device modification to a diagnostic ultrasound device can be made without the need for submission of a new premarket notification (510(k)) submission. As before, device sponsors who comply with the applicable premarket notification requirements 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) (Ref. 2). When finalized, this draft guidance is applicable to diagnostic ultrasound devices under 21 CFR 892.1550 (Ultrasonic pulsed doppler imaging system), 21 CFR 892.1560 (Ultrasonic pulsed echo imaging system), and 21 CFR 892.1570 (Diagnostic ultrasonic transducer).

## 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 "Diagnostic Ultrasound Systems and Transducer 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. This guidance is not subject to Executive Order 12866.

## 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

<https://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 "Marketing Clearance of Diagnostic Ultrasound Systems and Transducers; Draft Guidance for Industry and Food and Drug Administration Staff" may send an email request to [CDRH-Guidance@fda.hhs.gov](mailto: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 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, the collections of information in 21 CFR part 820 have been approved under OMB control number 0910-0073, and the collections of information in 21 CFR part 801 have been approved under OMB control number 0910-0485. The collections of information in 21 CFR parts 1002 and 1010 are approved under OMB control number 0910-0025.

#### V. References

The following references are on display in the Dockets Management Staff (see ADDRESSES) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <https://www.regulations.gov>. FDA has verified the website address, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

1. FDA Guidance, "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." Available at:

<https://www.fda.gov/downloads/UCM070911.pdf>.

2. FDA, "Information for Industry." Available at: <https://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/ucm115357.htm>

Dated: September 22, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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