

*Estimated Total Burden Hours:* 5,418.

**Authority:** 42 U.S.C. 1310.

**Mary B. Jones,**

*ACF/OPRE Certifying Officer.*

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## 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 June 27, 2019.

**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.<sup>1</sup>

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 [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 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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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2019–N–0075]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Experimental Study on Measuring Consumer Comprehension of Displays of Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by July 29, 2019.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910–NEW and title “Experimental Study on Measuring Consumer Comprehension of Displays of Harmful and Potentially Harmful

Constituents in Tobacco Products and Tobacco Smoke.” Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Experimental Study on Measuring Consumer Comprehension of Displays of Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke OMB Control Number 0910–NEW

<sup>1</sup> Available at <https://www.fda.gov/downloads/Radiation-EmittingProducts/RadiationEmitting>

[ProductsandProcedures/MedicalImaging/UCM509874.pdf](https://www.fda.gov/downloads/ProductsandProcedures/MedicalImaging/UCM509874.pdf).