4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-D-2565]

The 510(k) Third Party Review Program; Guidance for Industry, Food and Drug Administration Staff, and Third Party Review Organizations; 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 "510(k) Third Party Review Program." This guidance provides a comprehensive look into FDA's current thinking regarding the 510(k) Third Party (3P510k) Review Program authorized under the Federal Food, Drug, and Cosmetic Act (FD&C Act). Under the FDA Reauthorization Act of 2017 (FDARA), FDA was directed to issue guidance on the factors that will be used in determining whether a class I or class II device type, or subset of such device types, is eligible for review by an accredited person. The 3P510k Review Program is intended to allow review of devices by 3P510k Review Organizations in order to provide manufacturers of these devices an alternative review process that allows FDA to best utilize our resources on higher risk devices.

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-2016-D-2565 for "510(k) Third Party Review Program." 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.govinfo.gov/content/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 "510(k) Third Party Review Program" to the Office of Policy, 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: Gregory Pishko, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3441, Silver Spring, MD 20993-0002, 240-402-6635.

SUPPLEMENTARY INFORMATION:

I. Background

FDA's implementation of section 523 of the FD&C Act (21 U.S.C. 360m) establishes a process for recognition of qualified third parties to conduct the initial review of premarket notification (510(k)) submissions for certain low-to-moderate risk devices eligible under the 3P510k Review Program. Under FDARA (Pub. L. 115-52), the criteria used to establish device eligibility in the 3P510k Review Program changed and FDA was directed to issue guidance on the factors that will be used in determining whether a class I or class II device type, or subset of such device types, is eligible for review by an accredited person. The objectives of this guidance

are to describe the factors FDA will use in determining device type eligibility for review by 3P510k Review Organizations; to outline FDA's process for the recognition, rerecognition, suspension and withdrawal of recognition for 3P510k Review Organizations; and to ensure consistent quality of work among 3P510k Review Organizations through Medical Device User Fee Amendments IV commitments authorized under FDARA in order to eliminate the need for routine, substantive re-review by FDA. This guidance also outlines FDA's current thinking on leveraging the International Medical Device Regulators Forum's requirements for Regulatory Reviewers under the Good Regulatory Review Practices and the Medical Device Single Audit Program.

FDA considered comments received on the draft guidance that appeared in the *Federal Register* of September 14, 2018 (83 FR 46742). FDA revised the guidance as appropriate in response to the comments. This guidance supersedes "Implementation of Third Party Programs Under the FDA Modernization Act of 1997; Final Guidance for Staff, Industry, and Third Parties" issued on February 2, 2001, and "Guidance for Third Parties and FDA Staff; Third Party Review of Premarket Notifications" issued on September 28, 2004.

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 the 510(k) Third Party Review Program. 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 https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm. This guidance document is also available at https://www.regulations.gov. Persons unable to download an electronic copy of "510(k) Third Party Review Program" may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 17-028 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. 3501-3521). The collections of information in the following FDA regulations and guidance have been approved by OMB as listed in the following table:

21 CFR Part or Guidance	Topic	OMB Control No.
807	Medical Devices: Third-Party Review under FDAMA	0910-0375
807, subpart E	Premarket notification	0910-0120
"Center for Devices and Radiological Health (CDRH) Appeals Processes"	CDRH Appeals Process	0910-0738
"Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff"	Q-submissions	0910-0756

Dated: March 9, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020-05080 Filed: 3/11/2020 8:45 am; Publication Date: 3/12/2020]