



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-D-1387]

Expansion of the Abbreviated 510(k) Program: Demonstrating Substantial Equivalence Through Performance Criteria; Draft Guidance for Industry and Food and Drug Administration Staff; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled "Expansion of the Abbreviated 510(k) Program: Demonstrating Substantial Equivalence Through Performance Criteria; Draft Guidance for Industry and Food and Drug Administration Staff." This draft guidance provides FDA's current thinking on expanding the abbreviated 510(k) program for demonstrating substantial equivalence for premarket notification (510(k)) submissions. The intent of the draft guidance is to describe an optional program for certain well understood device types, where a submitter could demonstrate that a new device meets FDA-identified performance criteria instead of directly comparing the performance of the new device to a specific, submitter-identified predicate device as part of a demonstration of substantial equivalence. This draft guidance is not final nor is it in effect at this time.

DATES: Submit either electronic or written comments on the draft guidance by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure

that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.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-2018-D-1387 for "Expansion of the Abbreviated 510(k) Program: Demonstrating Substantial Equivalence Through Performance Criteria; 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 docket, 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 "Expansion of the Abbreviated 510(k) Program: Demonstrating Substantial Equivalence Through Performance Criteria; 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; or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: *For Center for Devices and Radiological Health-regulated devices:* Sonja Fulmer, Office of the Center Director, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5421, Silver Spring, MD 20993-

0002, 301-402-5979. *For Center for Biologics Evaluation and Research-regulated devices:* Stephen Ripley, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA has explained and clarified, through the guidance entitled, "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]" (Ref. 1), how it makes substantial equivalence decisions under section 513(i)(1)(A) of the Federal, Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360c(i)(1)(A)). Substantial equivalence is rooted in comparisons between new devices and predicate devices. However, the FD&C Act does not preclude FDA from using performance criteria to facilitate this comparison. If a legally marketed device performs at certain levels relevant to its safety and effectiveness, and a new device meets or exceeds those levels of performance for the same characteristics, FDA could find the new device as safe and effective as the legally marketed device. Instead of reviewing data from direct comparison testing between the two devices, FDA could support a finding of substantial equivalence with data showing the new device meets or exceeds the level of performance of appropriate predicate device(s). Under the approach expanded in this guidance, a submitter could satisfy the requirement to compare its device with a legally marketed device by, among other things, demonstrating conformance to performance criteria established in FDA-recognized consensus standards, FDA guidance, and/or special controls.

Use of this approach may also streamline the review of 510(k) submissions, thereby reducing burdens on the Agency and possibly review times on individual submissions. In addition, this approach may facilitate healthcare professionals and patients making better

informed decisions, by helping ensure a device cleared through this pathway meets a transparent set of performance criteria. At the same time, this approach satisfies the statutory standard for demonstrating substantial equivalence. As a result, this expanded approach is intended to promote the public health by helping patients gain more timely access to new medical devices that are high quality, safe, and effective. FDA welcomes public input on device types for which FDA should consider identifying performance criteria and evidence-based suggestions on what the performance criteria should be.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (§ 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on "Expansion of the Abbreviated 510(k) Program: Demonstrating Substantial Equivalence Through Performance Criteria; Draft Guidance for Industry and Food and Drug Administration Staff." 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>. This draft guidance document is also available at either <https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm> or <https://www.regulations.gov>. Persons unable to download an electronic copy of

"Expansion of the Abbreviated 510(k) Program: Demonstrating Substantial Equivalence Through Performance Criteria; Draft Guidance for Industry and Food and Drug Administration Staff" may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 17038 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 and guidance. 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 807, subpart E have been approved under OMB control number 0910-0120 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.

V. Reference

The following reference is on display in the Dockets Management Staff (see ADDRESSES) and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is 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. "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]--Guidance for Industry and Food and Drug Administration Staff," July 28, 2014, available at:

<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM284443>.

Dated: April 9, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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