4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-D-0900]

Benefit-Risk Factors to Consider When Determining Substantial Equivalence in Premarket Notifications (510(k)) with Different Technological Characteristics; 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 final guidance entitled "Benefit-Risk Factors to Consider When Determining Substantial Equivalence in Premarket Notifications (510(k)) with Different Technological Characteristics." This guidance document describes factors FDA considers when evaluating the benefit-risk profile of a device in comparison to a predicate device in a 510(k) when the device has the same intended use as the predicate device, and different technological characteristics that do not raise different questions of safety and effectiveness. This guidance can be helpful in situations when there is an increase in risk and increase or equivalent benefit, or a decrease in benefit and a decrease or equivalent risk when comparing a new device to a predicate device. FDA developed this guidance to improve the predictability, consistency, and transparency of the 510(k) premarket review process.

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-2014-D-0900 for "Benefit-Risk Factors to Consider When Determining Substantial Equivalence in Premarket Notifications (510(k)) with Different Technological Characteristics." 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 "Benefit-Risk Factors to Consider When Determining Substantial Equivalence in Premarket Notifications (510(k)) with Different Technological Characteristics" 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: Ifeanyi Uwemedimo, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1609, Silver Spring, MD 20993-0002, 240-402-5243.

SUPPLEMENTARY INFORMATION:

I. Background

Submitters seeking 510(k) submission must demonstrate to FDA that the new device is substantially equivalent (SE) to a legally marketed predicate device using the criteria identified in section 513(i) of the FD&C Act (21 U.S.C. 360c(i)). To find a new device SE to a predicate device, FDA must first find that the devices have the same intended use. FDA must then determine that the devices have the same technological characteristics, or that any differences in technological characteristics do not raise different questions of safety and effectiveness, and that the new device is as safe and effective as the predicate device.

FDA evaluates differences in technological characteristics between the new device and the predicate device to determine their effect on substantial equivalence (i.e., whether the new device is as safe and effective as the predicate device). Under section 513(a)(2) of the FD&C Act, FDA determines the safety and effectiveness of a device by weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use, among other relevant factors.

This guidance document is consistent with FDA guidance entitled "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]" (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM284443), issued on July 28, 2014, and provides additional clarification on factors that FDA takes into consideration when evaluating the benefit-risk profile of a new device in comparison to a predicate device when FDA must evaluate whether the new device is substantially equivalent to the predicate device. More specifically, in situations where (1) an increase in risk and increase or equivalent benefit or (2) a decrease in benefit and a decrease or equivalent risk when comparing a new device to a predicate device, FDA recommends that a benefit-risk

assessment be conducted to provide further perspective regarding whether the new device is substantially equivalent to the predicate. FDA does not recommend a benefit-risk assessment in situations where there is (1) an increase in risk and decrease in benefit or (2) decrease or equivalent risk and increase or equivalent benefit because benefit-risk factors are not warranted to determine whether a device is substantially equivalent. This guidance does not add new regulatory requirements for submitters, it does not change the 510(k) premarket review standard, nor does it create extra or new burdens on what has traditionally been submitted in 510(k)s.

In the *Federal Register* on July 15, 2014 (79 FR 41289), FDA announced the availability of the draft guidance and interested parties were invited to comment by October 14, 2014. FDA has considered all the public comments received prior to finalizing this guidance.

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 benefit-risk factors to consider when determining substantial equivalence in premarket notifications (510(k)) with different technological characteristics. 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/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/defau

lt.htm. This guidance document is also available at https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm or https://www.regulations.gov. Persons unable to download an electronic copy of "Benefit-Risk Factors to Consider When Determining Substantial Equivalence in Premarket Notifications (510(k)) with Different Technological Characteristics" may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 1818 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 table:

21 CFR Part or Guidance	Topic	OMB Control No.
807, subpart E	Premarket notification	0910-0120
"Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff"	Q-submissions	0910-0756
803	Medical Devices; Medical Device Reporting; Manufacturer reporting, importer reporting, user facility reporting, distributor reporting	0910-0437

Dated: September 19, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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