



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-D-2021]

Deciding When To Submit a 510(k) for a Software Change to an Existing Device; 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 guidance entitled “Deciding When to Submit a 510(k) for a Software Change to an Existing Device.” FDA is issuing this final guidance document to clarify when a software change in a legally marketed medical device would require that a manufacturer submit a premarket notification (510(k)) to FDA. FDA is correcting an error in the docket number assigned to the “Deciding When to Submit a 510(k) for a Software Change to an Existing Device” notice of availability when it published in the *Federal Register* (81 FR 52441, August 8, 2016). The docket number currently is FDA-2011-D-0453. FDA is changing the docket number to FDA-2016-D-2021. This action is administrative in nature and is being taken to avoid any potential confusion in the docket.

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-2021 for “Deciding When to Submit a 510(k) for a Software Change to an Existing Device.”

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 “Deciding When to Submit a 510(k) for a Software Change to an Existing Device” 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: Linda Ricci, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G634, Silver Spring, MD 20993-0002, 301-796-6325, linda.ricci@fda.hhs.gov; and Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

A 510(k) is required when a legally marketed device subject to 510(k) requirements is about to be significantly changed or modified in design, components, method of manufacture, or

intended use. Significant changes or modifications are those that could significantly affect the safety or effectiveness of the device, or major changes or modifications in the intended use of the device (§ 807.81(a)(3) (21 CFR 807.81(a)(3))). This guidance will aid manufacturers of medical devices who intend to make a software modification to a 510(k)-cleared device or other device subject to 510(k) requirements, such as a preamendments device or a device that was granted marketing authorization via the De Novo classification process under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(f)(2)) (also referred to together as “existing devices”), during the process of deciding whether the software modification exceeds the regulatory threshold of § 807.81(a)(3) for submission and clearance of a new 510(k).

This guidance specifically addresses software design and technology modifications, including firmware. This guidance does not apply to software for which the Agency has stated in guidance that it does not intend to enforce compliance with applicable regulatory controls (e.g., “Mobile Medical Applications: Guidance for Industry and FDA Staff,” issued February 9, 2015, available on the internet at <https://www.fda.gov/downloads/medicaldevices/.../ucm263366.pdf>) and software that does not meet the definition of a medical device at section 201(h) of the FD&C Act (21 U.S.C. 321(h)).

In the *Federal Register* on August 8, 2016, FDA announced the availability of the draft guidance and interested parties were requested to comment by November 7, 2016. FDA considered comments received on the draft guidance and revised the guidance as appropriate.

This guidance is not intended to implement significant policy changes to FDA’s current thinking on when submission of a new 510(k) is required for a software change to an existing device. Rather, the intent of this guidance is to enhance the predictability, consistency, and transparency of the “when to submit” decision-making process by providing a least burdensome

approach, and describing in greater detail the regulatory framework, policies, and practices underlying such a decision, specifically as it relates to software changes. The recommendations discussed in this guidance for evaluating when a software change to an existing device would trigger the requirement that a manufacturer submit a new 510(k) to the Agency are consistent with the least burdensome principles (Refs. 1 and 2). This guidance applies the least burdensome principles, in part, by reliance on risk management and the quality system regulation (21 CFR part 820) to determine whether submission of a new 510(k) is required for a software change to an existing device.

Elsewhere in this issue of the *Federal Register*, FDA is announcing the availability of the guidance document entitled “Deciding When to Submit a 510(k) for a Change to an Existing Device,” to aid manufacturers of medical devices who intend to make non-software changes to an existing device during the process of deciding whether the modification exceeds the regulatory threshold of § 807.81(a)(3) for submission and clearance of a new 510(k).

## 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 “Deciding When to Submit a 510(k) for a Software Change to an Existing Device.” 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/default.htm>. Guidance documents are also available at <https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <https://www.regulations.gov>. Persons unable to download an electronic copy of “Deciding When to Submit a 510(k) for a Software Change to an Existing Device” 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 1500055 to identify the guidance you are requesting.

#### IV. Paperwork Reduction Act of 1995

This 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 820 are approved under OMB control number 0910-0073; the collections of information in 21 CFR part 807, subpart E are approved under OMB control number 0910-0120; the collections of information in 21 CFR part 803 are approved under OMB control number 0910-0437; and the collections of information in 21 CFR parts 801 are approved under OMB control number 0910-0485.

#### 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 addresses, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

1. “The Least Burdensome Provisions of the FDA Modernization Act of 1997: Concept and Principles,” dated October 4, 2002, available at:  
<https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm085999.pdf>.
2. “Suggested Format for Developing and Responding to Deficiencies in Accordance with the Least Burdensome Provisions of FDAMA,” dated November 2, 2000, available at:  
<https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073680.pdf>.

Dated: October 20, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017-23196 Filed: 10/24/2017 8:45 am; Publication Date: 10/25/2017]