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4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2024-D-1528]

Transfer of a Premarket Notification (510(k)) Clearance--Questions and Answers; 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 titled "Transfer of a Premarket Notification (510(k)) Clearance--Questions and Answers." This guidance provides information on the most frequently asked questions regarding the transfer or sale of a 510(k) clearance from one 510(k) holder to another.

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-2024-D-1528 for "Transfer of a Premarket Notification (510(k)) Clearance--Questions and Answers." 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, 240-402-7500.

- 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, 240-402-7500.

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 titled "Transfer of a Premarket Notification (510(k)) Clearance--Questions and Answers" to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5441, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Erica Takai, Center for Devices and Radiological Health, Food and Drug Administration, 301-796-6353; or Phillip Kurs, Center for Biologics Evaluation and Research, Food and Drug Administration, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document titled "Transfer of a Premarket Notification (510(k)) Clearance--Questions and Answers." This guidance provides information on the most frequently asked questions regarding the transfer or sale of a 510(k) clearance from one 510(k) holder to another. An owner or operator of an establishment who is engaged in the manufacture, preparation, propagation, compounding, assembly, or processing of a device intended for human use is generally required to register the establishment and submit listing information for all devices in commercial distribution.[1] Under section 510(k) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and its implementing regulations, any person required to register under section 510 (21 U.S.C. 360) and 21 CFR 807.20 must generally submit a premarket notification submission, or "510(k)," if the device is being introduced into commercial distribution for the first time, or the device is one that the person currently has in commercial distribution or is reintroducing into commercial distribution, but that is about to be significantly changed or modified in design, components, method of manufacture, or intended use.[2]

When a 510(k) clearance for a specific device is sold or transferred from one person to another, if the new 510(k) holder is engaged in any of the activities requiring listing, 21 CFR 807.25 requires the new 510(k) holder to list their device in FDA's electronic device registration and listing system.[3] When listing, if the device is not significantly changed or modified in design, components, method of manufacture, or intended use,[4] the new 510(k) holder must enter the original FDA-assigned premarket submission number unless submitting a new 510(k), in

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[1] 21 CFR 807.20(a); see FD&C Act subsections 510(b), 510(i), and 510(j). Any foreign establishment engaged in the manufacture, preparation, propagation, compounding, or processing of a device that is imported or offered for import into the United States is required to register and list in conformance with the procedures in 21 CFR 807.40, 21 CFR 807.41, and subpart B of 21 CFR Part 807. The registration requirement does not apply to owners or operators that are exempt under section 510(g) of the FD&C Act or subpart D of 21 CFR Part 807.

[2] See section 510(k) of the FD&C Act; see also section 513(i), 21 CFR sections 807.20, 807.81(a), and FDA's guidance documents "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications," "Deciding When to Submit a 510(k) for a Change to an Existing Device," and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device."

[3] 21 CFR 807.25.

[4] For discussion about changes or modifications to existing devices that could require submission of a new 510(k), see FDA's guidance document titled "Deciding When to Submit a 510(k) for a Change to an Existing Device" and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device."

which case the new 510(k) holder would supply the new FDA-assigned premarket submission number, in FDA's electronic device registration and listing system.[5] If the new 510(k) holder has significantly changed or modified the device in design, components, method of manufacture, or intended use, the new 510(k) holder must generally submit a new 510(k), and, when listing following clearance of the new 510(k), would enter the new FDA-assigned premarket submission number in FDA's electronic device registration and listing system.[6] The new 510(k) holder must, if not previously entered into an operation described in 21 CFR 807.20(a), register within 30 days after entering into such an operation and submit device listing information, including the FDA-assigned cleared 510(k) premarket notification submission number,[7] at that time.[8] When a 510(k) clearance for a specific device is sold or transferred from one person to another, the labeler must submit an update to the information required by 21 CFR 830.310 by using the Global Unique Device Identification Database (GUDID) if such information (for example, the name of the labeler) has changed.[9] If you fail to register, list, update GUDID information, or submit a marketing application when required, your device may be considered adulterated and/or misbranded.[10]

A notice of availability of the draft guidance appeared in the *Federal Register* of June 5, 2025 (90 FR 23937). FDA considered comments received and revised the guidance as appropriate in response to the comments, including clarifying terminology and further explaining 510(k) holder requirements.

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[5] The new 510(k) holder need not submit a new 510(k) because the new 510(k) holder is not proposing "to begin the introduction or delivery for introduction into interstate commerce for commercial distribution" of the device. See 21 CFR 807.81(a) and 42 FR 42523 (August 23, 1977); see also 21 CFR 807.85(b)(2) (applies to those distributors and repackagers who are exempt from submitting a 510(k) if it was filed by another person).

[6] 21 CFR 807.25.

[7] Id.

[8] 21 CFR 807.22(a). See 21 CFR 807.22 for other registration and listing timing requirements.

[9] 21 CFR 830.310(a)(1) and 830.330(b)("The labeler of a device shall submit to FDA an update to the information required by § 830.310 whenever the information changes. The updated information must be submitted no later than the date a device is first labeled with the changed information. If the information does not appear on the label of a device, the updated information must be submitted within 10 business days of the change.")

[10] See FD&C Act sections 501(f)(1)(B), 502(a)(1), 502(o), and 502(t)(2).

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 "Transfer of a Premarket Notification (510(k)) Clearance--Questions and Answers." 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.

II. 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, https://www.fda.gov/regulatory-information/search-fda-guidance-documents, or https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics. Persons unable to download an electronic copy of "Transfer of a Premarket Notification (510(k)) Clearance--Questions and Answers" may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number GUI00001808 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521). The collections of information in the following table have been approved by OMB:

21 CFR Part; Guidance; or FDA Form	Topic	OMB Control No.
807, subpart E	Premarket notification	0910-0120
807, subparts A through D	Electronic Submission of Medical Device Registration and Listing	0910-0625

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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