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Transfer of a Premarket Notification (510(k)) Clearance – Questions and Answers

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

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Document issued on June 5, 2025.

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For questions about this document regarding CDRH-regulated devices, contact the Premarket Notification (510(k)) Staff at 301-796-5640.

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For general questions regarding the FDA Unified Registration and Listing System (FURLS)/Device Registration and Listing Module (DRLM), please contact Registration and Listing at reglist@cdrh.fda.gov or 301-796-7400, Option 1.

U.S. FOOD & DRUG ADMINISTRATION

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

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Preface

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Transfer of a Premarket Notification (510(k)) Clearance – Questions and Answers

Draft Guidance for Industry and Food and Drug Administration Staff

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. 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. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

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. 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 21 CFR 807.20 who plans to introduce a device into commercial distribution for the first time must, per 21 CFR 807.81(a)(2), submit a premarket notification submission, or "510(k)," if that device is not exempt from 510(k) requirements.[1] This guidance discusses topics related to a transfer or sale of a 510(k) clearance in which the submission of a new 510(k) would not be required, and instances in which entities must use the existing 510(k) number to list a device.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

[1] See section 510(k) of the FD&C Act; also see section 513(i), 21 CFR sections 807.20, 807.81(a), and the 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."

II. Background and Scope

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.[2] Under section 510(k) of the FD&C Act, each person who is required to register their establishment must generally submit a 510(k) to FDA at least 90 days before proposing to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use if the device is being introduced into commercial distribution for the first time.[3]

When a 510(k) clearance for a specific device is sold or transferred from one person to another, the new 510(k) holder must list their device in the FDA Unified Registration and Listing System (FURLS)/ Device Registration and Listing Module (DRLM), an internet-based registration and listing system, if engaged in activities requiring listing.[4] When listing, if the device is not significantly changed or modified,[5] the new 510(k) holder must supply the original FDA-assigned premarket submission number[6] unless submitting a new 510(k), in which case the new 510(k) holder would supply the new FDA-assigned premarket submission number.[7] 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 submission number,[8] at that time.[9] A device manufactured, prepared, propagated, compounded, or processed in an establishment that is not duly registered under section 510, or a device that is not included in a list required by section 510(j), is misbranded.[10]

The transfer or sale of a 510(k) clearance may require label updates, including revisions to the

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[2] 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.

[3] 21 CFR 807.81(a)(2); also see FD&C Act section 513(i). Note that a 510(k) is not required for a device for which a premarket approval application under section 515 of the FD&C Act, or for which a petition to reclassify under section 513(f)(2) of the FD&C Act, is pending before FDA, or there is a predetermined change control plan (PCCP) cleared under section 515C of the FD&C Act, provided that the change is consistent with the PCCP. 21 CFR 807.81(b)(1).

[4] 21 CFR 807.25.

[5] For discussion about changes or modifications to existing devices that could require submission of a new 510(k), see the guidance documents "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."

[6] 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).

[7] 21 CFR 807.25(g)(4).

[8] Id.

[9] 21 CFR 807.22(a). See 21 CFR 807.22 for other registration and listing timing requirements.

[10] See FD&C Act section 502(o).

name and place of business of the manufacturer, packer, or distributor.[11] Labelers must also ensure that, in general, the label of every medical device and every device package bear a unique device identifier (UDI).[12] In addition, 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 via the Global Unique Device Identification Database (GUDID) if such information (for example, the name of the labeler) has changed.[13] For more information about GUDID requirements, see the "Global Unique Device Identification Database (GUDID)" guidance and FDA's webpage, "Global Unique Device Identification Database (GUDID)."[14]

For further information about registering and listing via FURLS/DRLM, see the webpage, "How to Register and List." See the website, "FDA Industry Systems," for information about other FDA databases, such as the CDRH Export Certification Application and Tracking System (CECATS).

III. Definitions

For purposes of this guidance, we will use the following definitions:

510(k) holder: The person who possesses the 510(k) clearance for a device. For purposes of this guidance, the 510(k) holder is a singular owner.[15]

Contract manufacturer: Manufactures a finished device for or on behalf of a specifications developer or any other person.[16]

Contract sterilizer: Sterilizes a device for or on behalf of a specifications developer or any other person.[17]

Initial importer: Any importer who furthers the marketing of a device from a foreign manufacturer to the person who makes final delivery or sale of the device to the ultimate consumer or user, but does not repackage, or otherwise change the container, wrapper, or labeling of the device or device package.[18]

Labeler: (1) Any person who causes a label to be applied to a device with the intent that the device will be commercially distributed without any intended subsequent replacement or modification of the label; and (2) Any person who causes the label of a device to be replaced or modified with the intent that the device will be commercially distributed without any subsequent replacement or modification of the label, except that the addition of the name of, and contact

[11] 21 CFR 801.1(a).
[12] 21 CFR Part 801, subpart B and 21 CFR Part 830; see the guidance document, "Unique Device Identification System: Form and Content of the Unique Device Identifier (UDI)."
[13] 21 CFR 830.310(a)(1) and 830.330(b).
[14] See also FDA's webpage, "Global Unique Device Identification Database (GUDID)."
[15] See the guidance document "Deciding When to Submit a 510(k) for a Change to an Existing Device."
[16] See 21 CFR 807.20(a)(2).
[17] Id.
[18] 21 CFR 807.3(g).

information for, a person who distributes the device, without making any other changes to the label, is not a modification for the purposes of determining whether a person is a labeler.[19]

Manufacturer: Makes by chemical, physical, biological, or other procedures, any article that meets the definition of "device" in Section 201(h) of the FD&C Act.[20]

Person: Includes individuals, partnerships, corporations, and associations as defined under section 201(e) of the FD&C Act.

Relabeler: Changes the content of the labeling from that supplied from the original manufacturer for distribution under the establishment's own name. A relabeler does not include establishments that do not change the original labeling but merely add their own name.

Remanufacturer: Processes, conditions, renovates, repackages, restores, or does any other act to a finished device that significantly changes the finished device's performance or safety specifications, or intended use.[21]

Repackager: Packages finished devices from bulk or repackages devices made by a manufacturer into different containers. A repackager does not include an entity that only places finished packaged devices into shipping containers for transportation.

Reprocessor of single-use devices: An entity that performs additional processing and manufacturing on a single-use device that was previously used on a patient for the purpose of an additional single use on a patient.[22]

Specification developer: Initiates specifications for a device that is manufactured by a second party for subsequent commercial distribution by the person initiating specifications.[23]

IV. Questions and Answers

1. Who needs to submit a 510(k) to FDA?

You are required to submit a 510(k) if your device is subject to the requirements arising under section 510(k) of the FD&C Act[24] and you are a:

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[19] See 21 CFR 801.3.
[20] See 21 CFR 807.3(d).
[21] See 21 CFR 820.3(w); also see FDA's guidance, "Remanufacturing of Medical Devices."
[22] See section 201(ll) of the FD&C Act. See also section 510(o) of the FD&C Act and 21 CFR 807.20(a)(4).
[23] See 21 CFR 807.3(d)(3).
[24] Any person required to register under 21 CFR 807.20 who plans to introduce a device into commercial distribution for the first time must, per 21 CFR 807.81(a)(2), submit a 510(k) if that device is not exempt from premarket notification requirements. The registration requirement pertains to any person who is engaged in the manufacture, preparation, propagation, compounding, assembly, or processing of a device intended for human use. See also 21 CFR 807.81, "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."

a. Domestic manufacturer introducing a device to the U.S. market. Finished device manufacturers subject to the requirements arising under section 510(k) must submit a 510(k) if they manufacture a device according to their own specifications and market it in the U.S., including accessories to finished devices that are ready to be used for any intended health-related purpose and packaged or labeled for commercial distribution for such health-related purpose.[25]

b. Remanufacturer.

c. Reprocessor of single-use devices.

d. Specification developer.[26]

e. Foreign manufacturer.[27]

You may also be required to submit a 510(k) if you currently have a device in commercial distribution or are reintroducing it into commercial distribution and the device is about to be significantly changed or modified in design, components, method of manufacture, or intended use.[28]

Once FDA finds your device to be substantially equivalent to a legally marketed device, you become the "510(k) holder."

2. Can there be more than one simultaneous 510(k) holder per device?

Because there can only be one entity proposing to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device,[29] FDA believes there can be only one 510(k) holder for a device at a time.

3. Who can use a 510(k) holder's 510(k) number to list a device?

Anyone who is required to list a cleared device, including contract manufacturers, contract sterilizers, repackagers, and relabelers, must use the FDA-assigned 510(k) number of the cleared 510(k) to list the device.[30] The 510(k) holder is also responsible for complying with applicable requirements arising under the FD&C Act.

Initial importers may fulfill their listing obligation for any device for which they did not initiate or develop the specifications for the device or repackage or relabel the device by submitting the name and address of the manufacturer.[31]

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[25] 21 CFR 807.20(a)(6); see FDA's website "Premarket Notification 510(k)."
[26] The specification developer, subject to the requirements arising under section 510(k), as opposed to the contract manufacturer, must submit the 510(k).
[27] See 21 CFR 807.20(a) and 21 CFR 807.40(a).
[28] See 21 CFR 807.81(a)(3); also see "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."
[29] See 21 CFR 807.81(a)(2) and 807.85(b)(2).
[30] 21 CFR 807.25(g)(4).
[31] 21 CFR 807.20(a)(5).

4. I obtained a cleared 510(k) from another company (via transfer, sale, etc.). Do I need to submit a new 510(k)?

As noted above, when a 510(k) clearance for a specific device is sold or transferred from one person to another and the device is not significantly changed or modified in design, components, method of manufacture, or intended use,[32] the new 510(k) holder does not need to submit a new 510(k), if the new 510(k) holder would not be proposing "to begin the introduction or delivery for introduction into interstate commerce for commercial distribution" of a device.[33] See question 5 below for more details about the obligations of the 510(k) holder regarding a transfer or sale of a 510(k).

5. What obligations do I have to report the purchase, sale, or other transfer of a 510(k) clearance?

Establishment Registration

A new owner or operator not previously entered into an operation described in 21 CFR 807.20(a) must register via FURLS/DRLM within 30 days after entering into such an operation.[34]

Importantly, FDA may utilize FURLS/DRLM to identify any person who is engaged in the manufacture, preparation, propagation, compounding, assembly, or processing of a device in its postmarket surveillance efforts, including, for example, to timely notify a firm of the need to begin immediately a recall of a device that presents a risk of illness or injury.[35]

Device Listing

Each device listing for a 510(k)-cleared device requires inclusion of the FDA-assigned premarket submission number of the cleared 510(k).[36] If not previously entered into an operation described in 21 CFR 807.20(a), the new 510(k) holder must submit device listing information when registering, which must occur within 30 days after entering into such an operation.[37] The new 510(k) holder must, every fiscal year, during the period beginning on October 1 and ending on December 31, report any new device listings that were not previously reported, including any devices that are the subject of the newly acquired 510(k) clearances.[38]

A previous 510(k) holder that ceases to perform an activity on or to the device that had previously been identified on the device listing (for example, manufacturing the device) must update such device listing.[39] In addition, an owner or operator who discontinues commercial

[32] For discussion about changes or modifications to existing devices that could require submission of a new 510(k), see FDA's guidance documents "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."
[33] See 21 CFR 807.81(a) and 42 FR 42523 (August 23, 1977); see also 21 CFR 807.85(b)(2).
[34] See 21 CFR 807.22(a).
[35] See 21 CFR 7.45(a), (b).
[36] 21 CFR 807.25(g)(4).
[37] 21 CFR 807.22(a).
[38] 21 CFR 807.22(b)(3).
[39] 21 CFR 807.28(a).

distribution of a device must discontinue the device listing using FURLS/DRLM.[40]

UDI/Labeling Requirements

Any entity that meets the definition of a labeler must meet Unique Device Identification requirements, including, in general, having the UDI on the label of the device prior to commercial distribution.[41] Labelers must also submit timely updates of certain information into GUDID.[42]

If you fail to register, list, update GUDID information, or submit a marketing application as required, your device might be considered adulterated and/or misbranded.[43]

FDA commonly receives requests from individuals noting that a 510(k) clearance has been transferred to that individual from a previous 510(k) holder, and asking FDA to update the information. However, it is the responsibility of the owner or operator to ensure that it is meeting the registration and listing requirements of the FD&C Act. FDA is not required to update registration or listing information in response to such notifications.

An entity wishing to have a copy of a 510(k) may ask the prior owner for a copy of all documents, or may submit a Freedom of Information Act (FOIA) request.[44] Additionally, CDRH posts 510(k) records previously released to the public through FOIA requests in the 510(k) database available on the FDA's website.[45]

[40] 21 CFR 807.28(d).
[41] 21 CFR Part 801, subpart B and 21 CFR Part 830; see the guidance document, "Unique Device Identification System: Form and Content of the Unique Device Identifier (UDI)."
[42] 21 CFR 830.330(b).
[43] See FD&C Act sections 501(f)(1)(B), 502(a)(1), 502(o), and 502(t)(2).
[44] For more information, see FDA's webpage "CDRH FOIA: How to Get Records from CDRH."
[45] See 510(k) Premarket Database, available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm.

Guidance History	Date	Description
Level 1 Draft Guidance	June 2025	See Notice of Availability for more information.**

**The Notice of Availability is accessible via the Search for FDA Guidance Documents webpage.

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