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

Guidance for Industry and Food and Drug Administration Staff

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See additional PRA statement in Section VII of the guidance.

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

For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010.

For questions regarding the FDA Unified Registration and Listing System, 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

Preface

Public Comment

You may submit electronic comments and suggestions at any time for Agency consideration to https://www.regulations.gov. Submit written comments to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852. Identify all comments with the docket number FDA-2014-D-1837. Comments may not be acted upon by the Agency until the document is next revised or updated.

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CDRH

Additional copies are available from the Internet. You may also send an e-mail request to CDRH-Guidance@fda.hhs.gov to receive a copy of the guidance. Please use the document number 1808 to identify the guidance you are requesting.

CBER

Additional copies of this guidance are also available from the Center for Biologics Evaluation and Research (CBER), Office of Communication, Outreach, and Development (OCOD), 10903 New Hampshire Avenue, WO71, Rm. 3128, Silver Spring, MD 20993, or by calling 1-800-835-4709 or 240-402-8010, by email, ocod@fda.hhs.gov, or from the Internet at http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

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Guidance for Industry and Food and Drug Administration Staff

This guidance represents 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 how to notify FDA of the transfer of a 510(k) clearance from one person to another, and the procedures FDA and industry should use to ensure public information in FDA's databases about the current 510(k) holder for a specific device(s) is accurate and up-to-date.

FDA's guidance documents, including this guidance, 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.

II. Background and Scope

According to 21 CFR 807.81(a)(2), each person who is required to register his establishment pursuant to 21 CFR 807.20 must submit a premarket notification (510(k)) to FDA at least 90 days before he proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use when the device is being introduced into commercial distribution for the first time by that person, if the device is subject to 510(k) requirements.[1] However, when a 510(k) clearance for a specific device is

[1] See Federal Food, Drug, and Cosmetic Act (FD&C Act) sections 510(k), 513(i), and 515 (21 U.S.C. §§ 360(k), 360c(i), and 360e) and 21 CFR 807.81(a)(2).

sold or transferred from one person to another and the device is not significantly changed or modified, FDA does not expect the submission of a new 510(k).[2] For discussion about changes or modifications to existing devices that could require submission of a new 510(k), see FDA's guidance document entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device", available at https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm514771.pdf. FDA commonly receives notifications from individuals claiming that a 510(k) clearance has been transferred to them from a previous 510(k) holder. Tracking such transfers, however, has been challenging because FDA has been unable to identify and contact all previous 510(k) holders to establish a sequence of historical transfers of a particular 510(k). Until recently, FDA's databases did not reflect changes in the 510(k) holder that occurred after FDA's clearance of the 510(k). This was in part because 510(k) holders were not required to list their devices by 510(k) number, which made it difficult for FDA to tie a particular 510(k) to its current holder. Lack of updated, accurate 510(k) holder information created a number of challenges for FDA, current 510(k) holders, future 510(k) submitters, and other stakeholders.

The Food and Drug Administration Amendments Act of 2007 (FDAAA) (Pub. L. 110-85) amended section 510 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) by requiring domestic and foreign device establishments to begin submitting their registration and device listing information to FDA by electronic means rather than on paper forms,[3] and also specified the timeframes within which establishments are required to submit such information.[4] In accordance with FDAAA, the Agency launched FDA's Unified Registration and Listing System (FURLS), an Internet-based registration and listing system, which can be found at https://www.access.fda.gov/oaa/.[5]

On August 2, 2012, FDA modified the regulations in 21 CFR Part 807 to reflect statutory amendments to the device registration and listing provisions of the FD&C Act.[6] FDA also added a requirement that the FDA-assigned premarket submission number of cleared 510(k) devices be included with device listing information.[7] When an owner or operator creates a listing for a 510(k) device as a manufacturer, specification developer, repackager/relabeler, single-use device reprocessor, or remanufacturer, this signals to FDA that they are the likely current 510(k) holder for that device, because these establishment types are most typically 510(k) holders. Listing information is required to be updated at least annually[8] and there may only be one 510(k) holder for a device at a time;[9] therefore, this helps FDA identify current 510(k) holder information by 510(k) number.

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[2] See 21 CFR 807.81(a) and 42 FR 42523 (August 23, 1977).

[3] See FD&C Act section 510(p) (21 U.S.C. § 360(p)).

[4] See FD&C Act sections 510(b)(2), (i), and (j) (21 U.S.C. §§ 360(b)(2), (i), and (j)).

[5] See 77 FR 45927 (August 2, 2012).

[6] Ibid.

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

[8] See FD&C Act section 510(j)(2) (21 U.S.C. § 360(j)(2)) and 21 CFR 807.22.

[9] See FD&C Act section 510(k) (21 U.S.C. § 360(k)) and 21 CFR Part 807.

This guidance is not intended to address questions regarding other specific actions or processes in FURLS, the impact of a 510(k) transfer on other FDA databases (e.g., CDRH Export Certification Application and Tracking System (CECATS), Global Unique Device Identifier Database (GUDID)), nor is it intended to address the identification and tracking of a 510(k) holder for devices no longer listed.

III. Definitions

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

1. **"510(k) device"**

    - a device which was found to be substantially equivalent to another device under sections 513(f)(1) and 513(i) of the FD&C Act (21 U.S.C. §§ 360c(f)(1) and (i)).

2. **"Person"**

    - includes individuals, partnerships, corporations, and associations as defined under section 201(e) of the FD&C Act (21 U.S.C. § 321(e))

3. **"510(k) holder"**

    - the person who possesses the 510(k) clearance for a device (an FDA determination that a particular device has been found to be substantially equivalent to another device under sections 513(f)(1) and 513(i) of the FD&C Act) (21 U.S.C. §§ 360c(f)(1) and (i))

IV. Access to Current 510(k) Holder Information

1. **How can I obtain information on the current holder of a 510(k) that is under the purview of CDRH if I know the 510(k) number?**

To find information about the current holder of a CDRH 510(k):

- Locate the CDRH 510(k) database (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm)
- Type the 510(k) number in the "510K Number" field[10]
- Click on the "Search" button

The CDRH 510(k) database is publicly available. FDA has linked the 510(k) database to FURLS, which provides the most up to date information available on the current holder of a 510(k). By linking the CDRH 510(k) database to FURLS, FDA is using information from

[10] Other terms entered into this search function may also locate the 510(k) and the current holder of the 510(k), but using the 510(k) number when available is recommended as the most efficient way to obtain this information.

the FURLS database to provide the most up-to-date information available on the current holder of a 510(k).

2. How can I obtain information on the current holder of a 510(k) that is under the purview of CBER if I know the 510(k) number[11]?

Information about the current holder of a CBER 510(k) should also be available in the CDRH 510(k) database as described above for CDRH 510(k)s. If you cannot locate the 510(k) in the CDRH 510(k) database, information is also available on CBER's website. (http://www.fda.gov/BiologicsBloodVaccines/ucm121134.htm)

V. Questions and Answers on Notifying FDA of a Transfer of a 510(k) Clearance and Registering in FURLS

1. When should I report that I have bought, sold, or otherwise transferred a 510(k) clearance?

As discussed above, as a result of the launch of the FURLS Device Registration and Listing Module (DRLM) and the changes to the registration and listing regulations that became effective on October 1, 2012,[12] the medical device listing information provided to FDA has changed. Notification to FDA of a sale or other transfer of a 510(k) clearance is accomplished via compliance with listing requirements through use of FURLS. Owners and operators of medical device establishments that market 510(k)-cleared devices must supply the FDA-assigned premarket submission number of the cleared 510(k) when they list their devices in FURLS.[13] This allows FDA to identify the holder of each 510(k) based on the records created by manufacturers, specification developers, repackagers/relabelers, single-use device reprocessors, or remanufacturers in the FURLS DRLM. Because contract manufacturers and sterilizers, foreign exporters, and foreign private label distributors are generally not 510(k) holders, they generally list the product under their customer's 510(k) number once it has been listed by the 510(k) holder. Any entity that fails to list as required renders the device misbranded.[14]

New establishments are required to register and list within 30 days of entering into an operation described in 21 CFR 807.20(a).[15] In addition, 510(k) holders are required to review and update their Registration[16] and Listing[17] information at least annually. Persons may also

[11] Please note that CBER's 510(k) submission numbers begin with "BK."

[12] See 77 FR 45927 (August 2, 2012).

[13] See 21 CFR 807.25(g)(4).

[14] See FD&C Act section 502(o) (21 U.S.C. § 352(o)).

[15] See 21 CFR 807.22(a).

[16] See FD&C Act section 510(b)(2) (21 U.S.C. § 360(b)(2)) (Domestic) and 21 CFR 807.22(b)(1); FD&C Act section 510(i) (21 U.S.C. § 360(i)) (Foreign).

[17] See FD&C Act section 510(j)(2) (21 U.S.C. § 360(j)(2)) and 21 CFR 807.22(b)(3).

update their Registration and Listing information at other times, for example subsequent to a sale or purchase of a 510(k), instead of waiting for the requisite annual update.[18] There is no fee additional to the annual registration fee for such updates.

2. What happens if more than one establishment type that is typically the 510(k) holder lists a particular device under the same 510(k) number?

If there are listings that leave it uncertain who is the 510(k) holder for a particular device, the database will show the person who listed their device most recently until the issue is resolved. FDA will contact each of the persons that appear to be the 510(k) holder and attempt to determine the rightful 510(k) holder. In the event of a dispute, a court order, attestation from a previous, uncontested 510(k) holder, legal instrument such as a contract or will, and/or other documentation of the sequence of historical transfers of the 510(k) clearance, up to and including the current holder, may be submitted as evidence to establish the current 510(k) holder and to support updating the information in the FURLS database. The person determined not to be the 510(k) holder would be in violation of the FD&C Act if they were marketing a device without required 510(k) clearance.

3. Who should maintain information documenting the transfer of a 510(k) clearance?

We recommend that the current 510(k) holder maintain information documenting the transfer of a 510(k) clearance in its 510(k) files.

When a 510(k) is transferred, the entity transferring the 510(k) ceases to hold the 510(k). The new 510(k) holder is responsible for compliance with the regulatory requirements applicable to that person.

4. What if I am a distributor placing a device into commercial distribution for the first time under my name, or a repackager placing my own name on a device?

Per 21 CFR 807.85(b)(2), a distributor who places a device into commercial distribution for the first time under his own name and a repackager who places his own name on a device and does not change any other labeling or otherwise affect the device is exempted from premarket notification requirements if a premarket notification submission was filed by another person.

VI. Question and Answer about CLIA Categorizations

What should I submit upon transfer of a 510(k) clearance to ensure the CLIA categorization of my device is accurate?

[18] See 21 CFR 807.22(b)(4).

FDA is responsible for the categorization of commercially marketed in vitro diagnostic tests under the Clinical Laboratory Improvement Amendments of 1988 (CLIA).[19] FDA recommends that when the name of a cleared device changes, or the name of the manufacturer or distributor changes, the manufacturer should submit the updated label to FDA so FDA can ensure that the CLIA categorization of the device is accurate and update its record of the categorized test with the appropriate 510(k) holder and device information. See "Guidance for Industry and FDA Staff: Administrative Procedures for CLIA Categorization," available at https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070889.pdf. The new 510(k) holder should submit a letter to the Agency (at U.S. Food and Drug Administration, Center for Devices and Radiological Health, Document Mail Center – WO66-G609, 10903 New Hampshire Avenue, Silver Spring, MD 20993-0002) citing the 510(k) number, and identifying the submission as a CLIA Categorization Update. The new 510(k) holder should include a copy of the package insert that will be distributed with the device.

VII. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that 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 time required to complete this information collection is estimated to average 0.25 hours per response for voluntary reporting of transfer of 510(k) clearance on FDA's Unified Registration and Listing System (outside of annual listing reporting requirement, see OMB# 0910-0625) and 4 hours per response for submission of 510(k) transfer documentation when more than one party lists the same 510(k). This includes the time to review instructions, search existing data sources, gather the data needed, and complete and review the information collection. Send comments regarding this burden estimate to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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[19] See 64 FR 73561 (December 30, 1999).