

1 **Transfer of a Premarket Notification**
2 **(510(k)) Clearance – Questions and**
3 **Answers**

5 **Draft Guidance for Industry and**
6 **Food and Drug Administration Staff**

8 *DRAFT GUIDANCE*

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12 **Document issued on December 22, 2014.**

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23 Notification (510(k)) Staff at 301-796-5640.

25 For questions about this document regarding CBER-regulated devices, contact the Office of
26 Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-7800.

28 For questions regarding the FDA Unified Registration and Listing System, please contact
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32 **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

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44 CDRH-Guidance@fda.hhs.gov to receive a copy of the guidance. Please use the document
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46

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53 [http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInform](http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm)
54 [ation/Guidances/default.htm](http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm).

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65 *This draft guidance, when finalized, will represent the Food and Drug Administration's*
66 *(FDA's) current thinking on this topic. It does not create or confer any rights for or on*
67 *any person and does not operate to bind FDA or the public. You can use an alternative*
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70 *Office responsible for implementing this guidance. If you cannot identify the appropriate*
71 *FDA staff, call the appropriate number listed on the title page of this guidance.*

72 **I. Introduction**
73

74 This draft guidance provides information on how to notify FDA of the transfer of a 510(k)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

78
79 FDA's guidance documents, including this guidance, do not establish legally enforceable
80 responsibilities. Instead, guidances describe the Agency's current thinking on a topic and
81 should be viewed only as recommendations, unless specific regulatory or statutory
82 requirements are cited. The use of the word *should* in Agency guidances means that
83 something is suggested or recommended, but not required.

84 **II. Background**

85 Each person who is required to register must obtain FDA clearance of a premarket
86 notification (510(k)) prior to introducing or delivering for introduction into interstate
87 commerce for commercial distribution a device intended for human use that is not 510(k)-
88 exempt.¹ However, when a 510(k) clearance for a specific device is sold or transferred from

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), 807.100(a).

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89 one person to another and the device is not significantly changed or modified, FDA does not
90 expect the submission of a new 510(k).² FDA commonly receives notifications from
91 individuals claiming that a 510(k)-clearance has been transferred to them from a previous
92 510(k) holder. Tracking such transfers, however, has been challenging because FDA has
93 been unable to identify and contact all previous 510(k) holders to establish a sequence of
94 historical transfers of a particular 510(k). Until recently, FDA's databases did not reflect
95 changes in the 510(k) holder that occurred after FDA's clearance of the 510(k). This was in
96 part because 510(k) holders were not required to list their devices by *510(k) number*, which
97 made it difficult for FDA to tie a particular 510(k) to its current holder. Lack of updated,
98 accurate 510(k) holder information created a number of challenges for FDA, for current
99 510(k) holders, future 510(k) submitters, and other stakeholders.

100
101 The Food and Drug Administration Amendments Act of 2007 (FDAAA) (Pub. L. 110-85)
102 amended section 510 of the FD&C Act by requiring domestic and foreign device
103 establishments to begin submitting their registration and device listing information to FDA
104 by electronic means rather than on paper forms,³ and also specified the timeframes within
105 which establishments are required to submit such information.⁴ In accordance with FDAAA,
106 the agency launched FDA's Unified Registration and Listing System (FURLS), an Internet-
107 based registration and listing system.⁵

108
109 On August 2, 2012, FDA modified the regulations in 21 CFR part 807 to reflect statutory
110 amendments to the device registration and listing provisions of the FD&C Act.⁶ FDA also
111 added a requirement that the FDA-assigned premarket submission number of cleared 510(k)
112 devices be included with device listing information.⁷ When an owner or operator creates a
113 listing for a 510(k) device as a manufacturer, specification developer, repacker/relabeler,
114 single-use device reprocessor, or remanufacturer, this signals to FDA that they are the current
115 510(k) holder for that device, because these entities are responsible for the commercial
116 distribution of the device. Listing information is required to be updated at least annually⁸ and
117 there may only be one 510(k) holder for a device at a time;⁹ therefore, this provides FDA
118 with current 510(k) holder information by 510(k) number.

119 **III. Definitions**

120 For purposes of this guidance, we will use the following definitions:
121
122

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 See *id.*

⁷ See 21 CFR 807.25(g)(4).

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

⁹ See FD&C Act section 510(k) (21 U.S.C. § 360(k)) and 21 CFR 807.81(a).

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123 **1. “510(k) device”**

- 124
125 • a device which was found to be substantially equivalent to another device under
126 sections 513(f)(1) and 513(i) of the FD&C Act (21 U.S.C. §§ 360c(f)(1) and (i))
127

128 **2. “Person”**

- 129
130 • includes individuals, partnerships, corporations, and associations as defined under
131 section 201(e) of the FD&C Act (21 U.S.C. § 321(e))
132

133 **3. “510(k) holder”**

- 134
135 • the person who possesses the 510(k) clearance for a device (an FDA determination
136 that a particular device has been found to be substantially equivalent to another device
137 under sections 513(f)(1) and 513(i) of the FD&C Act) (21 U.S.C. §§ 360c(f)(1) and
138 (i))

139 **IV. Access to Current 510(k) Holder Information**

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

142
143 To find information about the current holder of a CDRH 510(k):
144

- 145 • Locate the [CDRH 510\(k\) database](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm)
146 (<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>)
147 • Type the 510(k) number in the “510K Number” field¹⁰
148 • Click on the “Search” button
149 • FDA plans to link the 510(k) database to FURLS, which will provide the most up to
150 date information available on the current holder of a 510(k).
151

152 The CDRH 510(k) database is publicly available. By linking the CDRH 510(k) database to
153 FURLS, FDA is using information from the FURLS database to provide the most up-to-date
154 information available on the current holder of a 510(k).
155

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

158
159 Information about the current holder of a CBER 510(k) should also be available in the CDRH
160 510(k) database as described above for CDRH 510(k)s. If you cannot locate the 510(k) in the

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.

161 CDRH 510(k) database, information is also available on [CBER's website](http://www.fda.gov/BiologicsBloodVaccines/ucm121134.htm).
162 (<http://www.fda.gov/BiologicsBloodVaccines/ucm121134.htm>)

163 **V. Questions and Answers on Notifying FDA of a** 164 **Transfer of a 510(k) Clearance**

165 **1. When should I report that I have bought, sold, or otherwise transferred a 510(k)** 166 **clearance?**

167
168 Notification of FDA of a sale or other transfer of a 510(k) clearance, whether or not the
169 device is already on the market, is accomplished via compliance with listing requirements.
170 As discussed above, as a result of the launch of the FURLS Device Registration and Listing
171 Module (DRLM) and the changes to the registration and listing regulations that became
172 effective on October 1, 2012,¹¹ the medical device listing information provided to FDA has
173 changed. Owners and operators of medical device establishments that market 510(k)-cleared
174 devices must now supply the FDA-assigned premarket submission number of the cleared
175 510(k) when they list their devices in FURLS.¹² This allows FDA to easily identify the holder
176 of each 510(k) based on the records created by manufacturers, specification developers,
177 repackers/relabelers, single-use device reproducers, or remanufacturers in FURLS DRLM.
178 Because contract manufacturers and sterilizers, foreign exporters, and foreign private label
179 distributors are not responsible for the commercial distribution of devices, they would not be
180 510(k) holders, and should list the product under their customer's 510(k) number once it has
181 been listed by the 510(k) holder. Any entity that fails to list as required renders the device
182 misbranded.¹³

183
184 New establishments are required to register and list within 30 days of entering into an
185 operation described in 21 CFR 807.20(a).¹⁴ In addition, 510(k) holders are required to review
186 and update their Registration¹⁵ and Listing¹⁶ information at least annually. Persons may also
187 update their Registration and Listing information at other times, for example subsequent to a
188 sale or purchase of a 510(k), instead of waiting for the requisite annual update.¹⁷ There is no
189 fee additional to the annual registration fee for such updates.

190 191 **2. What happens if more than one person claims to be the 510(k) holder for a** 192 **particular device at the same time?**

193
194 If two persons claim to be the 510(k) holder for a particular device, for example by
195 registering and listing the same 510(k) number during the same annual registration and listing

¹¹ See 77 FR 45927 (August 2, 2012).

¹² See 21 CFR 807.25(g)(4).

¹³ See FD&C Act sections 502(o) and 510(j) (21 U.S.C. §§ 352(o) and 360(j)).

¹⁴ See 21 CFR 807.22(a).

¹⁵ 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).

¹⁶ See FD&C Act section 510(j)(2) (21 U.S.C. § 360(j)(2)) and 21 CFR 807.22(b)(3).

¹⁷ See 21 CFR 807.22(b)(4).

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196 period, the database will show the person who listed their device most recently until the issue
197 is resolved. FDA will contact both persons claiming to be the 510(k) holder and attempt to
198 determine the rightful 510(k) holder. In the event of a dispute, a court order, attestation from
199 a previous, uncontested 510(k) holder, legal instrument such as a contract or will, and/or
200 other documentation of the sequence of historical transfers of the 510(k) clearance, up to and
201 including the current holder, may be submitted as evidence to establish the current 510(k)
202 holder and support updating the information in the FURLS database. The person determined
203 not to be the 510(k) holder would be in violation of the FD&C Act if they were marketing a
204 device without required 510(k) clearance.

205
206 **3. Who should maintain information documenting the transfer of a 510(k) clearance?**

207
208 We recommend that the current 510(k) holder maintain information documenting the transfer
209 of a 510(k) clearance in its 510(k) files.

210 **VI. Question and Answer about CLIA Categorizations**

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

213
214 FDA is responsible for the categorization of commercially marketed in vitro diagnostic tests
215 under the Clinical Laboratory Improvement Amendments of 1988 (CLIA).¹⁸ FDA
216 recommends that where the name of a cleared device changes, or the name of the
217 manufacturer or distributor changes, the manufacturer should submit the updated label to
218 FDA so FDA can ensure that the CLIA categorization of the device is accurate and update its
219 record of the categorized test with the appropriate 510(k) holder and device information. See
220 “[Guidance for Industry and FDA Staff: Administrative Procedures for CLIA Categorization](#),”
221 available at
222 [http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/uc](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070762.htm)
223 [m070762.htm](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070762.htm). The new 510(k) holder should submit a letter to the Agency (at U.S. Food
224 and Drug Administration, Center for Devices and Radiological Health, Document Mail
225 Center – WO66-G609, 10903 New Hampshire Avenue, Silver Spring, MD 20993-0002)
226 citing the 510(k) number, and identifying the submission as a CLIA Categorization Update.
227 The new 510(k) holder should include a copy of the package insert that will be distributed
228 with the device.

229
230

¹⁸ See 64 FR 73561(December 30, 1999).