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FDA Issues Draft Guidance on 510(k) Transfers

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In late December 2014, FDA published a draft guidance entitled, "Transfer of a Premarket Notification (510(k)) Clearance – Questions and Answers," which provides information to industry on how to notify FDA of the transfer of a 510(k) clearance from one person to another. The draft guidance also outlines procedures that FDA staff and industry should use to ensure that public information in FDA databases (such as the database of 510(k) premarket notifications) about the current 510(k) holder for a specific device is accurate and up-to-date.

FDA explains in the draft guidance that, up to this point, the agency has found tracking 510(k) transfers to be difficult and has not been able to identify and contact all previous and current holders of 510(k) clearances to confirm the sequence of transfers. Some of this difficulty can be attributed to the fact that 510(k) holders were not required to list their devices by 510(k) number until October 2012, after FDA amended 21 C.F.R. Part 807 and launched the FDA's Unified Registration and Listing System (FURLS) Device Registration and Listing Module.

Under the draft guidance, FDA will rely on compliance with 21 C.F.R. § 807.25(g)(4), which requires that submissions of device listing information include FDA-assigned premarket submission numbers, to provide notification to the agency of any sales or other transfers of 510(k) clearances. The 510(k) holder can update its listing information subsequent to the sale or purchase of a 510(k), instead of waiting for the required annual update. A new establishment is required to register and list within 30 days of beginning an operation requiring registration. The new owner of a 510(k)

that has been purchased or transferred should maintain in its 510(k) files the information documenting the purchase or transfer of ownership.

Only one person may hold a 510(k) clearance at a time. In the event that more than one person claims to be the 510(k) holder for a particular device at the same time, FDA's database will show the person who listed the device most recently as the 510(k) holder until the issue is resolved. Although the draft guidance provides only minimal detail about the dispute resolution process, the draft guidance indicates that the agency will contact both persons claiming to be the 510(k) holder and attempt to determine the rightful holder.

The draft guidance also describes steps that should be taken upon the transfer of the 510(k) clearance for an in vitro diagnostic test to ensure that the device's CLIA categorization is accurate. The manufacturer should submit a letter to FDA citing the 510(k) number and stating that the submission is a CLIA Categorization Update, and should include an updated label if the cleared device's name, or the name of its manufacturer or distributor, changes.

Comments can be submitted electronically at regulations.gov. Comments on the regulatory framework draft guidance should be submitted by March 23, 2015, to Docket No. FDA-2014-D-1837.