FDA Releases Draft Guidance on 510(k) Transfers

Alan G. Minsk and Alexander B. Foster

On December 19 and 22, 2014, the Food and Drug Administration (FDA) released a draft guidance and a Federal Register notice, respectively, on the transfer of a medical device premarket notification application, commonly referred to as a 510(k).[1] The draft provides guidance to industry on how to notify FDA when a 510(k) marketing clearance is transferred and the procedures to ensure accurate and up-to-date information is included in FDA's databases. FDA is asking for comments on the draft guidance by March 23, 2015.

It has been common practice for a company to whom a 510(k) clearance has been transferred to notify FDA of the transfer. However, FDA has had difficulty tracking these transfers, in part because 510(k) holders have not been required to list their devices by 510(k) number. Thus, the agency cannot establish a sequence of historical transfers of a particular 510(k).

In providing guidance to current and future 510(k) holders and transferees, the draft guidance offers the following definition of a 510(k) holder:

> [T]he 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 [Federal Food, Drug, and Cosmetic] Act) (21 U.S.C. §§ 360c(f)(1) and (i))[.]

The draft guidance's most significant feature is the requirement that the owners and operators of medical device establishments that market 510(k)-cleared devices must now supply the FDA-assigned premarket submission number of the 510(k) when they list their devices in FDA's Unified Registration and Listing System, known as FURLS. Because of the change, the agency expects it will be able to identify the current 510(k) holder more easily with the submission number. The 510(k) holders will be required to update this listing information at least annually, and there may only be one 510(k) holder for a device at a time.

Because previously it was not uncommon for more than one firm to claim to be the 510(k) holder, the draft guidance states that, until the ownership issue for a specific medical device is resolved, the database will identify the most recent firm listed. FDA will then contact the other companies claiming to be the 510(k) holder in order to determine the rightful holder. If a further dispute occurs, FDA will allow for submission of evidence to determine the identity of the current holder. FDA notes that "[t]he person determined not to be the 510(k) holder would be in violation of the FD&C [Federal Food, Drug, and Cosmetic] Act if they were marketing a device without required 510(k) clearance."

1 Transfer of a Premarket Notification (510(k)) Clearance – Questions and Answers, Food and Drug Administration (Dec. 19, 2014), http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM427385.pdf; Transfer of a Premarket Notification (510(k)) Clearance – Questions and Answers, 79 Fed. Reg. 76,331 (Dec. 22, 2014).

Authors and Contributors

Alan G. Minsk
Partner, Atlanta Office
404.873.8690
alan.minsk@agg.com

Alexander B. Foster
Associate, Atlanta Office
404.873.8598
alex.foster@agg.com

not *if*, but *how*.®

About Arnall Golden Gregory LLP

Arnall Golden Gregory, a law firm with more than 150 attorneys in Atlanta and Washington, DC, employs a "business sensibility" approach, developing a deep understanding of each client's industry and situation in order to find a customized, cost-sensitive solution, and then continuing to help them stay one step ahead. Selected for The National Law Journal's prestigious 2013 Midsize Hot List, the firm offers corporate, litigation and regulatory services for numerous industries, including healthcare, life sciences, global logistics and transportation, real estate, food distribution, financial services, franchising, consumer products and services, information services, energy and manufacturing. AGG subscribes to the belief "not if, but how.®" Visit www.agg.com.

Atlanta Office
171 17th Street NW
Suite 2100
Atlanta, GA 30363

Washington, DC Office
1775 Pennsylvania Ave., NW,
Suite 1000
Washington, DC 20006

To subscribe to future alerts, insights and newsletters: **http://www.agg.com/subscribe/**