SQUIRE PATTON BOGGS

Food and Drug Administration (FDA) Issues Draft Guidance on Transfer of 510(k)s

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On June 5, 2025, the FDA issued draft guidance addressing frequently asked questions regarding the transfer or sale of a 510(k) clearance from one 510(k) holder to another. As transfer of 510(k)s is a common issue during transactions involving medical devices, this guidance, if finalized as written, will provide helpful insight regarding the FDA's position on the 510(k) requirements in the context of such transactions.

Background

Under the Federal Food, Drug and Cosmetic Act (FDCA), a 510(k) demonstrates that a device to be marketed is as safe and effective, that is, substantially equivalent, to a legally marketed device. Once the submitter receives approval of the 510(k) from the FDA, which is known as 510(k) clearance, s/he may proceed to market the device. The person who possesses the 510(k) clearance is the 510(k) holder. The FDA does not have any regulations governing the transfer of a 510K clearance. Nor has the FDA (to our knowledge) previously issued any draft or final industry guidance on the issue.

An owner or operator of an establishment who is engaged in the manufacture of a medical device is generally required to register the establishment and submit listing information for all devices in commercial distribution. Under section 510(k) of the FDCA, each person who is required to register their establishment must generally comply with premarket notification requirements. To do so, the person must submit a 510(k) to the FDA at least 90 days prior to the introduction or delivery of a device into interstate commerce if the device is being introduced into commercial distribution for the first time. In addition to the draft guidance, the FDA also recently issued step-by-step instructions for reporting a transfer of ownership of a device establishment subject to registration requirements.

We discuss the implications of these documents below.

Draft Guidance

The FDA has historically permitted the transfer of a 510(k), with the important limitation that two companies may not manufacture the same device under a single 510(k) clearance. Therefore, if a 510(k) holder wishes to license the right to manufacture a device but also wishes to continue its own manufacturing activity, the FDA has historically required the licensee to obtain a new 510(k) clearance. Because of this approach, buyers generally seek to obtain an agreement from the seller that it will cease manufacturing after the transfer of the 510(k) clearance. Furthermore, the seller typically agrees to transfer the 510(k) clearance to the buyer on an exclusive basis. A non-exclusive transfer of 510(k) clearance creates a risk in that the buyer will be required to obtain a new 510(k) clearance if another party is manufacturing under the same clearance number. The FDA's draft guidance aligns with this historic approach in stating that there can be only one 510(k) holder for a device clearance at a time; therefore, anyone who is required to list a cleared device must use a 510(k) holder's 510(k) number to list a device. This includes contract entities.

The FDA has also historically taken the position that it does not have the responsibility to track 510(k) clearance transfers, and that companies should not expect the agency to handle information regarding ownership transfers. For this reason, it is (and has been) advisable for a buyer to obtain a warranty that the seller owns the 510(k) clearance and has not previously transferred it to any other party. The FDA's guidance iterates the agency's historical approach and, therefore, the relevance of this warranty.

Also consistent with the FDA's historic approach, their guidance makes clear that when a 510(k) clearance for a specific device is sold or transferred from one person to another, the new 510(k) holder does not need to submit a new 510(k), so long as the device is not significantly changed or modified in design, components, method of manufacture or intended use as governed by the transferred 510(k). Examples of significant modifications that may require a new 510(k) submission include changes to intended use; sterilization method; material changes; or design changes. The draft guidance, thus, underscores the importance of the buyer conducting the necessary diligence to ensure the device being sold is being marketed in accordance with the 510K clearance. To assess this risk, the 510(k) buyer should obtain a list of all post-clearance modifications to the device and consider requesting a warranty that the existing 510(k) clearance is legally adequate for the device as currently manufactured and distributed, accounting for all modifications to the device after clearance. Otherwise, the buyer should be prepared to accept the risk that a new 510(k) notice will be required for post-clearance modifications.

One additional consideration when transferring a 510(k), that is not mentioned in the FDA's guidance, is the transfer of records. Of particular importance are the device master records (DMRs), which contain device specifications, manufacturing process specifications, quality procedures, packaging and labeling specifications and installation, maintenance, as well as servicing procedures (see 21 CFR 820.181). A transfer of either 510(k) clearance should include an agreement by the owner to transfer the DMRs and all other records generated pursuant to the FDA's regulations that are necessary to assure that the buyer can continue to manufacture and distribute the transferred device in compliance with the FDA's requirements.

Otherwise, the FDA's draft guidance is focused on ensuring (1) proper registration and listing of the device itself and (2) proper registration of the transferee with the FDA (e.g., as a manufacturer), if the transferee is not already registered in some manner.

For the first category of concern, the FDA provides in the draft guidance that when a 510(k) clearance is sold or transferred from one person to another, the new 510(k) holder must list their device in the FDA online registration and listing database (FURLS/DRLM). When entering the listing information, if the device is not significantly changed or modified, the new 510(k) holder must supply the original FDA-assigned premarket submission number, unless submitting a new 510(k), in which case the new 510(k) holder would supply the new FDA-assigned premarket submission number. For the second category of concern, the new 510(k) holder must, if not previously entered into an operation requiring registration and listing (such as manufacturing), register within 30 days after entering into such an operation and submit device listing information, including the FDA-assigned submission number, at that time.

The draft guidance explains that entities subject to 510(k) registration requirements include remanufacturers; reprocessors; specification developers; foreign manufacturers; domestic manufacturers introducing a device to the US market; and finished device manufacturers that manufacture a device according to their own specifications and market it in the US, including accessories to finished devices that are ready to be used for any intended health-related purpose, as well as packaged or labeled for commercial distribution for such health-related purpose.

The draft guidance provides the following additional clarifications:

- The 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.
- 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 the device listing. This update is required each fiscal year during the period beginning on October 1 and ending on December 31, though the update may also be completed at the time the change is made.
- Any entity that meets the definition of a labeler must meet Unique Device Identification (UDI) requirements, including, in general, having the UDI on the label of the device prior to commercial distribution. Labelers must also submit timely updates of certain information into the Global Unique Device Identifiers Database (GUDID).

The transfer of a 510(k) clearance may also require label updates, including updates to the name and place of business of the manufacturer, packer or distributor.

Conclusion

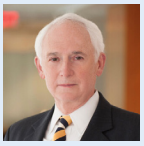
While the guidance does not alter the FDA's authority in the context of 510(k) transfer issues, or many of its historic practices, it clarifies the agency's rationale for timing and notification of 510(k) transfers and provides clarity on issues that commonly arise during device-related transactions.

The guidance is currently in draft form, and the FDA has solicited comments on the guidance through August 4, 2025. If you have any questions on the 510(k) process or may be interested in submitting a comment on the draft guidance, please contact us.

Contacts

Nicole E. Bothwell
Associate, Atlanta
T 1 678 272 3179
E nicole.bothwell@squirepb.com

Delia A. Deschaine
Partner, Washington DC
T 1 202 457 5661
E delia.deschaine@squirepb.com



John E. Wyand
Senior Partner, Washington DC
T 1 202 457 626 6676
E john.wyand@squirepb.com

Stephen E. Chelberg
Partner, Tokyo
T + 81 3 5774 1800
E stephen.chelberg@squirepb.com

Jennifer M. Tharp
Senior Associate, Cleveland
T 1 216 479 8537
E jennifer.tharp@squirepb.com