FDA Shows Displeasure with Leasing 510(k)s

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Every week, we review a number of Warning Letters – fortunately, we review others companies' enforcement letters more than having to respond for our clients. One recent Warning Letter issued by the Food and Drug Administration caught our eye, because this issue has come up before with clients – buying, selling or transferring a 510(k) versus leasing or licensing a cleared device to multiple firms. A recent Warning Letter, issued by a local district (not FDA headquarters), makes the distinction clear and describes what FDA allows.

FDA objected to the device company's "leasing" its 510(k) to other companies to manufacture products under the licensee firm's own label.[1] The agency said that leasing "is not recognized by FDA and should be discontinued." It distinguished such licensing agreements from those where a company contracts with distributors or private labelers to sell under its own 510(k). FDA wrote:

> A 510(k) may be bought, sold, or transferred. A 510(k) holder cannot lease or license a 510(k) cleared device to multiple firms. As such, FDA prohibits two companies from manufacturing the same device under a single 510(k) clearance. If a 510(k) holder wishes to license the right to manufacture a device but also wants to continue its own manufacturing activity, FDA's policy is to require the licensee to obtain a new 510(k) clearance. A 510(k) clearance is based upon a specific device; therefore, it is essential that the device described in the transfer agreement match the device described in the 510(k) clearance.
>
> Exclusivity should also be addressed in any transfer agreement with the licensor agreeing to cease manufacturing of the transferred device. The new owner should maintain information documenting the transfer of ownership of a 510(k), including any legal transactions that took place, in its 510(k) files. The new owner should also list the device according to 21 CFR, Part 807 and the previous owner should delete its device listing.

AGG Observations

1. While a district office issued the Warning Letter, it is rare that a district acts unilaterally, without at least having the Headquarter's review and input. So, in our opinion, while the case was fact-specific, the policy statement is intended for the entire industry.
2. FDA describes what it will and will not allow. It further explains the rationale.
3. The particular Warning Letter did not focus exclusively on the licensing issue; it was raised at the end. The enforcement was primarily issued for quality-related difficulties. While we cannot state definitively, the license was not the central concern but more of a 'while we have your attention, we will remind you and industry of our policy.' The case provided FDA an opportunity to reiterate its position.
4. A company cannot bootstrap marketing its own device under another company's 510(k). One must submit a new and separate 510(k). This is distinct from a company, such as a distributor selling another's product under the original 510(k). In the latter case; it is not a separate device as there is only one manufactured product.
5. Companies should document the transaction and ownership to minimize potential future confusion and regulatory risk.

1 We will not identify the company, but the Warning Letter may be accessed at www.fda.gov/iceci/enforcementactions/warningletters/ucm436674.htm.

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