

# The FDA Provides Clarity on Transferring a 510(k) Clearance

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On June 5, 2025, the FDA released a new [draft guidance](#) addressing frequently asked questions relating to the transfer-of-ownership process for 510(k) clearances. In particular, the guidance provides much needed clarity regarding the requirements for a proper transfer of a 510(k) or an acquisition (or other ownership change) of the 510(k)-holder. Read a summary of the key takeaways from the guidance below.

## **Are there specific FDA notice/consent obligations that must be met within a certain time before or after the transfer becomes effective?**

No. Unlike transfers of ownership involving various other types of FDA-issued marketing authorizations, no specific form or notice letter must be submitted to the FDA to affect a 510(k) transfer or otherwise update ownership information, nor is FDA approval required. Instead, the new 510(k)-holder will notify the FDA in a more indirect manner by updating its establishment registration and device listing (among other things) as detailed below.

## **Does the new 510(k)-holder have to submit a new 510(k) in connection with the transfer?**

Not usually. A new 510(k) clearance is only required in connection with an ownership change if: (1) the device is significantly changed or modified, or (2) the new 510(k)-holder would be introducing the device into commercial distribution for the first time.

## **What processes are required to properly acquire a 510(k)?**

The guidance details the establishment registration, device listing and device labeling requirements necessary for the proper transfer of a 510(k) clearance. Notably, the new 510(k)-holder—not the previous holder—must update the registration and listing information, as the FDA is not required to update the information in response to notifications made by the previous 510(k)-holder.

1. **Establishment Registration**: If the new 510(k)-holder is not already registered in the FDA's Unified Registration and Listing System (FURLS)/ Device Registration and Listing Module (DRLM), it must do so within 30 days after engaging in an operation listed in [21 CFR 807.20\(a\)](#).

### 2. **Device Listing Requirements**:

- **New Owner**: The new 510(k)-holder must list the acquired device under its Establishment Registration in FURLS/DRLM (For new registrants, this will be done as a step in the registration process). When updating the device listing, the new 510(k)-holder will use the original FDA-assigned premarket submission number. The only instance in which the new 510(k)-holder will update the device listing with a new premarket submission number is if there is a new 510(k) submission for the device (e.g., if there is a significant change or modification).

- **Previous Owner:** The previous 510(k)-holder must also update its existing Establishment Registration to de-list the transferred device. The same action is required in other instances where a 510(k)-holder discontinues commercialization or distribution of the FDA-cleared device (i.e., outside the context of a sale or transfer).

3. **Labeling/UDI Requirements**: In general, any entity that meets the definition of a “labeler” must meet all Unique Device Identification (UDI) requirements. In particular, before introducing a device into commerce, the new labeler must: (1) ensure the proper UDI is on all device labels, and (2) submit any applicable updates to the information listed in [21 CFR 830.310](#) via the Global Unique Device Identification Database (GUDID).

### **What penalties can arise if a new 510(k) owner does not properly register, list or label the device?**

A new 510(k)-holder could be subject to FDA enforcement if the required registration, listing and/or GUDID updates are not made in accordance with the guidance. Importantly, failure to comply with any of these required updates could render the device(s) marketed under the applicable 510(k) misbranded under the federal Food, Drug & Cosmetic Act, which could result in consequences beyond FDA enforcement, including (for example) contractual defaults, warranty breaches, and product liability and/or consumer-protection litigation, among other potentially material adverse effects.

### **Next Steps**

Comments to the draft guidance must be submitted by August 4, 2025. It remains to be seen whether this guidance will be finalized as expected or if it will share the same fate as the draft guidance issued on this topic in December 2014, which was withdrawn before being finalized. Our [FDA Regulatory and Compliance Team](#) will be closely monitoring any developments in relation to this guidance. Visit us [At The Counter](#) for further updates on this guidance or any other FDA-related matters of interest or contact any member of our team directly.