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Food, Drug & Device Law Alert - FDA Issues Draft Guidance On Direct Marking Of UDI On Devices

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The Food and Drug Administration (FDA) recently issued a draft guidance titled, "Unique Device Identification: Direct Marking of Devices." FDA's unique device identification (UDI) regulations require directly marking a UDI on a device if the device is intended to be used more than once and intended to be reprocessed before each use. Because such devices are intended to be reprocessed and reused, they will inevitably be separated from their original labels and device packages. Direct marking helps to ensure the ability to identify such devices throughout their useful life. The UDI regulations, however, do not define "intended to be used more than once" or "reprocessed" and this draft guidance includes FDA's interpretation of those key terms.

According to the draft guidance, FDA interprets "intended to be used more than once" to mean "intended for repeated uses on or by different patients, for example, where a device is cleared or approved and labeled for repeated uses on or by different patients." Further, FDA defines "reprocessing" as "validated processes used to render a medical device, which has been previously used or contaminated, fit for a subsequent use." The draft guidance distinguishes between mere cleaning and reprocessing by stating that "[i]f a device is intended only to be cleaned between uses by different patients, this would not be considered reprocessing for the purposes of the UDI direct marking requirements." Further, the direct marking requirement does not apply "[i]f the device is intended to be used more than once *on or by the same patient, and not on or by different patients*" (emphasis added).

The twelve page draft guidance addresses other important direct marking questions as well. For example, it discusses when direct marking will require a new 510(k) submission, pre-market approval (PMA) supplement, or biologics license application (BLA) supplement. For devices cleared through the 510(k) or *de novo* processes, the manufacturer must make a determination on whether the direct marking "could significantly" affect the safety or effectiveness of the device and document the determination in the design history file. If the answer is yes, an exception is available and FDA encourages manufacturers to take advantage of it. If the manufacturer nonetheless wants to directly mark the device, a new 510(k) submission is required. If the device was approved through a PMA or BLA and the direct marking "would affect" the safety or effectiveness of the device, then a new submission is required (i.e., the exception available to 510(k) cleared devices is *not* available to PMA or BLA approved devices). And yes, not surprisingly, the draft guidance states that user fees will apply to the supplements.

The draft guidance notes that FDA does not specify the method for directly marking a device. FDA expects directly marked UDI to last

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throughout the expected useful life of the device and suggests possible methods, depending on the nature of the device, such as etching, attaching a permanent plaque to durable equipment, or affixing a permanent tag such as a radio frequency identification (RFID) tag to the device.

The full UDI (both the device identifier and the production identifier) must be marked on the device (unless an exception applies, but the direct marking need not include both the plain text and automatic identification and data capture (AIDC) formats.

A copy of the draft guidance document, which addresses other questions as well, can be found here.

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