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FDA Issues Draft Guidance on 510(k) Device Modifications: New Emphasis on Potential Impact of Modifications

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On July 27, the Food and Drug Administration (FDA) issued a draft guidance titled "510(k) Device Modifications: Deciding When to Submit a 510(k) for a Change to an Existing Device."[1] Once finalized, the document will supersede the existing 1997 guidance on the same topic. Issuance of the draft guidance fulfills one of the proposals set forth in FDA's August 2010 blueprint for reform of the 510(k) clearance process. As drafted, the guidance could result in a significant increase in the number of 510(k) notifications filed for device modifications.

In its August 2010 report evaluating the 510(k) process, FDA expressed concern that manufacturers are only filing a 510(k) for modifications that "significantly affect the safety or effectiveness of the device," not for modifications that "*could* significantly affect the safety or effectiveness of the device." In other words, FDA's concern is that some manufacturers do not file a 510(k) if the change has the *potential* to affect the device's safety or effectiveness. Accordingly, the draft guidance emphasizes the requirement that manufacturers assess the potential of modifications to impact safety and effectiveness, which likely will result in a higher number of 510(k) submissions for modifications.

In addition to its emphasis on accounting for the potential impact of changes on safety or effectiveness, the structure and content of the draft guidance appear designed to limit the number and type of modifications that do not require submission of a 510(k). Provided below is a brief summary of certain provisions in the draft guidance that represent changes from the existing 1997 guidance and are likely to limit a manufacturer's ability to avoid submitting a 510(k) for a device modification:

- **Flow charts –** The draft guidance eliminates the flow charts that are included in the existing 510(k) modification guidance, and instead sets forth 10 questions that address four categories of changes: labeling changes, technology or performance changes, materials changes, and manufacturing process changes (a new category). FDA's elimination of the flow charts appears to be related to its objective of ensuring that manufacturers consider the potential impact of changes.

- **Device comparison –** The draft guidance states that the modified device should not be compared to any other device produced by the same manufacturer or another manufacturer. In other words,

1. View the full draft guidance online at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM265349.pdf.

a manufacturer cannot conclude that a modification to its "Device A" does not require a new 510(k) because that modification was cleared on manufacturer's "Device B." The modified device must be compared only to the most recently cleared unmodified version of the same device.

- **Labeling changes –** Significantly, the draft guidance suggests that manufacturers generally need not assess whether a change in the indications for use is "major." FDA states that all such changes are generally considered "major" changes to the intended use requiring submission of a new 510(k). The draft guidance also states that deletion of warnings and precautions, and changes in instructions for use, could warrant submission of a new 510(k).

- **Technology, engineering, and performance changes –** The draft guidance deletes the existing guidance's questions on operating principle and control mechanism, and instead asks whether the modification alters the fundamental scientific technology of the device. Additionally, it treats modifications in performance specifications, ergonomics or patient/user interface, dimensional specifications, and software/firmware as separate types of changes. Notably, the draft guidance asks a specific question regarding whether the change is being implemented to address a device risk or failure, and notes that such a change may require a correction or removal report. Finally, the draft guidance adds a series of questions intended to assess whether the change affects how the device is likely to be used in practice.

- **Materials changes –** The draft guidance focuses on all changes affecting patient-contacting materials (whether direct or indirect), rather than on changes that are likely to contact body tissues or fluids *in vivo*. Thus, there could be a significant increase in 510(k) submissions relating to materials changes as a result of this guidance document.

Comments on the draft guidance are due by October 25, 2011. If you have any questions on the issues discussed in this LawFlash or would like assistance in preparing comments to FDA, please contact the authors of this LawFlash, **M. Elizabeth Bierman** (202.739.5206; mebierman@morganlewis.com), **Phoebe Mounts** (202.739.5898; pmounts@morganlewis.com); or **Michele L. Buenafe** (202.739.6326; mbuenafe@morganlewis.com).

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