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## FDA drafts guidance on when a 510(k) is needed

JULY 26, 2011 Reed Miller

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**Silver Spring, MD** – The FDA is trying to help manufacturers avoid the mistake that Edwards made in the infamous **Myxo ring controversy** [1].

As reported by [heartwire](#), patient lawsuits have charged Edwards Lifesciences with improperly selling an investigational device because the company did not obtain a new premarket notification submission 510(k) clearance for the **Myxo ETlogix** annuloplasty ring. Edwards argued that the device did not require a new 510(k) because it was similar to a previously cleared version. The FDA disagreed but did not sanction Edwards.

To prevent companies in the future from improperly skipping the 510(k) process, the FDA has **drafted new guidance** to provide direction to manufacturers on when to submit a 510(k) for a modification of a previously cleared medical device.

The draft guidance is now open to public comment. It will supersede the 1997 version of this guidance. The new guidance is one of the fruits of the agency's ongoing exhaustive review of the 510(k) system. That process will reach a major milestone later this week when the **Institute of Medicine**, part of the **National Academies of Science**, releases **its long-awaited report on the 510(k) system**.

The draft guidance addresses questions related to software and other rapidly changing technologies while providing "greater clarity about changes that do not trigger the need for a new premarket submission," including examples of modifications that require a new 510(k) and changes that may simply be documented in accordance with a manufacturer's existing quality system.

"Even if labeling has not been affected, a new 510(k) submission should generally be submitted for modifications to device technology, engineering, and performance that significantly affect the cleared indications for use or fundamental technology of the existing device or that substantially change the performance characteristics or specifications of the device," the agency explains in the draft guidance. "These types of modifications encompass a broad span of changes, from minor engineering changes in a circuit-board layout to a change from electromechanical to microprocessor control of device function."

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**Source**


1. Food and Drug Administration. Guidance for industry and FDA staff 510(k) device modifications: Deciding when to submit a 510(k) for a change to an existing device. July 27, 2011. Available [here](#).

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