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Patient Safety

When Does Changing a Medical Device Trigger FDA Rules?

The FDA expects to finalize by Nov. 8 guidances on when changes to a medical device are significant enough to warrant a new approval, an agency official said.

Mike Ryan, a regulatory adviser in the Food and Drug Administration's device center, said Sept. 12 at a conference that a pair of draft guidances issued last summer aim to clarify when device manufacturers must submit a premarket notification—commonly known as a 510(k) clearance—for an already-approved device. The 21st Century Cures (Pub. L. 114-255) law enacted last year requires the FDA to issue the final guidances by Nov. 8—one year after comments were due for the drafts. ''We do intend to meet that goal,'' Ryan said.

The FDA has issued warning letters on companies that didn't submit a 510(k) for significant changes, April Veoukas, director of regulatory affairs for Abbott, said at the Regulatory Affairs Professionals Society's Regulatory Convergence Conference in Oxon Hill, Md. At the same time, device makers that choose to take a conservative approach and submit 510(k) applications for all changes unnecessarily delay important changes from getting to the market.

''An incorrect decision could potentially result in FDA's issuance of a warning letter or other enforcement action, including recall,'' Suzan Onel, attorney, Kleinfeld, Kaplan & Becker, LLP

Suzan Onel, an attorney with Kleinfeld, Kaplan & Becker, LLP who helps device makers with their 510(k) applications, told Bloomberg BNA companies are ultimately responsible for assessing changes to their devices and documenting their decisions if they concluded that certain changes didn't trigger the need for a new 510(k). ''An incorrect decision could render a device misbranded and/or adulterated and could potentially result in FDA's issuance of a warning letter or other enforcement action, including recall,'' Onel said in a Sept. 12 email.

Device makers are constantly tinkering with products to improve them, Ryan said. But FDA regulations (21 C.F.R. 80781a)(30)) require manufacturers to submit a 510(k) either for a brand new product or for any significant changes to an approved device. Even if those changes ultimately make the device safer, he said, a manufacturer would still need a 510(k) for changes that meet the threshold of the regulations.

When Changes Are Significant Ryan said the guidances aim to help define how that regulatory language of ''change or modification in the device that could significantly affect the safety or effectiveness of the device'' applies to particular situations.

''These terms are fairly interpretable,'' Ryan said at the conference. ''And that was actually done on purpose.''

While a change on a device like a ventilator may trigger a 510(k) requirement, making the same change on another device might not because that other device isn't a life-sustaining, life-supporting device. ''This language has to cover all of that,'' he said.

The FDA issued in August 2016 the draft guidance ''Deciding When to Submit a 510(k) for a Change to an Existing Device,'' along with the draft guidance ''Deciding When to Submit a 510(k) for a Software Change to an Existing Device.'' The software guidance included a flow chart industry may use to determine if device companies need a 510(k) for software modifications.

Second Revision Those draft documents are the FDA's second attempt to revise a 20-year-old document on determining when a device maker must submit a 510(k).

''The importance of the guidance cannot be underscored,'' Onel said about the original 1997 guidance, which included a discussion of the issues related to various types of changes and flow charts. ''The guidance was intended to strike a balance between assuring the safety and effectiveness of modified devices and allowing certain incremental product improvements to be implemented without FDA review.''

Jeffrey K. Shapiro, an attorney with Hyman, Phelps & McNamara, P.C. who also helps clients with their 510(k) submissions, told Bloomberg BNA the 1997 guidance has worked very well, but there was widespread objection to a 2011 attempt to revise the document. Ryan said the agency withdrew the 2011 version.

''The new draft guidances are an improvement,'' Shapiro said in a Sept. 12 email about the 2016 documents. ''They build on the structure of the 1997 guidance but add clarification based upon experience.''

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Software Guidance Helpful The new software guidance will be helpful, he added, because software changes have their own logic and the original guidance was written when software was less prevalent. ''These guidances may help reduce compliance disagreements between FDA and regulated firms about when a new 510(k) should have been filed for a modification,'' Shapiro said. ''Time will tell.''

Ryan said the FDA decided to keep the flow charts from the 1997 guidance based on consensus from the community. The agency is working to add more examples in response to feedback.

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More information on the regulatory convergence conference is available at http://www.raps.org/convergence2.aspx?id=27574#FDA. The draft guidance on device software changes is at http://src.bna.com/hui.The draft guidance on nonsoftware device changes is at http://src.bna.com/huh.

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