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The FDA's latest push to speed medtech approvals

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The FDA is rewriting the rules for medical technologies left, right and centre. Having released its proposals for bringing lab-developed tests under its umbrella earlier this month, and meanwhile working to bring in expedited device review, the agency is now beginning to codify the de novo classification process.

De novo approval permits companies to sidestep the premarket approval (PMA) process, but obtaining it is itself a lengthy course and thus is arguably more of a gamble than it has to be. The FDA's new proposals aim to streamline the process, removing steps and spelling out the information to include in a de novo submission. With luck, the slowdown of the past five years could soon be reversed (*FDA medtech approval slowdown hits surgical devices hardest, August 21, 2014*).

Under the current process, a company submits a 510(k) application specifying an approved predicate for its device. If the FDA determines that the device is so different from anything that came before as to have no predicate, it is automatically classified as a class III – high-risk – device, and the company will in most cases prepare and submit a PMA application.

Alternatively the manufacturer can request that the product be reclassified from class III into the lower-risk classes I or II. If the FDA turns this request down there is no alternative to the relatively burdensome PMA route.

If, though, the FDA agrees that the product poses a lower risk, the 510(k) is passed after all, despite the lack of a predicate, and the agency creates an entirely new category of devices. This is a de novo approval.

The two-step process – apply for a 510(k) and then seek reclassification – is arguably inelegant, but it is lengthy too. In some cases de novo approvals can take longer to pull off than PMAs, which, it might be said, renders the whole idea pointless. For example, ReWalk Robotics' powered exoskeleton took 12.3 months to complete the de novo process, *EvaluateMedTech* data show, whereas Medtronic's CoreValve won its PMA after just 5.8 months.

Changes

The most obvious point of the proposed changes is the elimination of the 510(k) submission step. Instead the 16-page document calls for the creation of a de novo application which manufacturers will submit instead. The agency has made a point of stipulating that this must include proof that a thorough search for a predicate has been made.

The draft guidance specifies three conditions that must be met for a device to stand a chance of de novo approval. There must be no identifiable predicate device; the device must pose low to moderate risk with reasonable assurance of its safety and effectiveness; and the company must set out its known risks and benefits, showing that the risks can be effectively mitigated and the effectiveness assured.

Under the proposed rules, if the FDA finds a predicate despite the company's avowals, a separate 510(k) will have to be filed. If the device is found to fall into class III, a PMA will be required.

If the product jumps through these hoops, however, the de novo approval will be granted and the device categorised as either class I or class II. A helpful flowchart on page 13 of the guidance document summarises the pathway.

The company will also have the option to file a pre-submission before the true de novo application, allowing it to obtain early feedback from the agency on the device's suitability. It would be a brave company that eschews this opportunity – in the initial months of implementation of the new rules, at least.

The beauty of the new plan is that it will be faster and cheaper for both parties. But manufacturers of low- and moderate-risk device makers should keep the champagne on ice for a while yet: the FDA has not given a date for implementation of the guidance, and the timescale is likely measured in years, not months. The de novo process ought to get faster – eventually.

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