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Device Modernization Series: FDA's Proposed De Novo Regulation

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In **our first Device Modernization series post**, we discussed how FDA is proposing to modernize the 510(k) review program. FDA also recently issued a proposed regulation for the De Novo program and linked that proposed regulation to 510(k) modernization efforts as part of a broader strategy to improve device safety.

The **proposed De Novo regulation**, issued December 5, 2018, would codify into regulation many of the policy and programmatic features of the De Novo program that are currently outlined in guidance documents. Because guidance is nonbinding, FDA is seeking through the proposed regulation to provide structure, clarity, and transparency to the De Novo process in a way that would be binding on De Novo submitters.

De Novo is a pathway to market for low-to-moderate-risk novel devices that would, because of their novelty and therefore lack of a predicate device, otherwise be required to pursue marketing authorization through the premarket approval process (i.e., by submitting a PMA). De Novos also, upon being granted, create a device classification that can be used by other manufacturers seeking to market similar devices through the 510(k) process. This is how FDA is linking De Novos with modernizing the 510(k) process. According to **FDA**:

> **The De Novo pathway provides a vehicle for establishing new predicates that can reflect modern standards for performance and safety and can serve as the basis for future clearances.**

That's true, though, regardless of whether the De Novo program requirements are in guidance or regulation. The proposed regulation simply offers a way for FDA to turn recommendations (in the many **De Novo-related guidance documents**) into requirements and to provide more clarity on what specific information is expected from a De Novo submitter. What's unclear is where FDA purports to get authority for some other requirements in the proposed rule. For example, the agency would like to "be able to inspect relevant facilities prior to granting or declining a De Novo request" but the Federal Food, Drug, and Cosmetic Act does not authorize inspections for De Novo classification requests. To the extent being the developer of a first-of-a-kind product is already burdensome from a regulatory perspective (not to mention the myriad other concerns like business strategy and protecting IP), this could disincentivize innovation by making follow-on devices seem even easier to get clearance. That's because other companies can use the De Novo classification to get their product to market via the 510(k) pathway, and 510(k) submitters are almost never subject to inspection. Further, the efficacy of a premarket inspection for a De Novo device is questionable considering many of the De Novo submitters are often startups without well-established manufacturing operations.

FDA's De Novo program has seen many changes in recent years, including the 2012 statutory change that allows direct De Novo submissions instead of first requiring a 510(k) to be found not substantially equivalent (NSE), and the introduction in 2017 of a user fee and review goals for De Novo submissions. The proposed rule is FDA's next step to fully developing the program. FDA is scheduled to take comments on the proposed rule until March 5, 2019.

The next and last post in our Device Modernization series will cover the ongoing discussions around laboratory developed tests (LDTs).

Authors