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A No-Predicate 510(k) Future? Pending US FDA Policy Might Forge A Path

by David Filmore

510(k) clearances are the US market on-ramp for most devices, and proving the device is similar enough to an already-marketed product is the entry toll. But a policy in development at FDA's device center offers an optional approach that avoids predicate comparisons. Center director Jeffrey Shuren says in an interview that he expects the new approach will become the "pathway of choice" for many companies, potentially upending what has been a defining characteristic of the device regulatory landscape for decades.

The process of comparing a new device to an already-marketed predicate device to prove substantial equivalence is a core driver of the US device market. It also aligns with the iterative innovation cycle, where products are continually updated to enhance outcomes and usability, that the device industry embraces.

But the reality, both FDA and industry say, is that it is proving increasingly difficult to show substantial equivalence between an advanced-technology approach to a problem and a device in the same general category that was developed several decades earlier.

Often, it requires firms to seek complicated combinations of predicates to connect the dots and show that a new technology does not raise new questions of safety and effectiveness, even in cases where information and data is available to support safety and effectiveness. (Also see "*Split Predicate? Nope, That's A 'Reference Device,' FDA Says*" - Medtech Insight, 3 Oct, 2011.)

At the same time, there has been a steady drum beat of complaints from the medical and consumer advocacy community that comparing new technologies to old devices is a recipe for putting unsafe products on the market. (Also see "*Scrutinizing 510(k)s: Critical Voices Get Heard In Congress*" - Medtech Insight, 16 Jul, 2007.)

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FDA says it thinks is has a solution to these grievances: A pathway that will give companies the opportunity, when appropriate, to compare their 510(k) device to objective performance and safety criteria defined in guidance documents or consensus standards, rather than against a predicate device. The result will be a process that is more streamlined for companies, but will produce more robust data supporting the device, says Jeff Shuren, director of the agency's Center for Devices and Radiological Health.

With the alternative 510(k) pathway, "you can say this is not your grandmother's devices, and this is not your grandmother's standard," CDRH Director Jeff Shuren says.

"It can be a win for the company, because it is much more straightforward," Shuren said in an interview. "It is a win for patients because they will have better data and higher confidence that the device that is coming on the market is safe and effective.

Shuren spoke to *Medtech Insight* about the plan of a draft guidance document that the agency plans to release in the coming months to outline the approach. (Also see "*New Path For 510(k)s On US FDA's FY 2018 Guidance-Priority Plan*" - Medtech Insight, 11 Dec, 2017.)

Although the approach will not be appropriate for all products and will certainly start with "low-hanging fruit," he says, Shuren expects it will start to overtake the conventional predicate pathway to 510(k) clearance. "We do think, over time, this alternative 510(k) pathway will become the pathway of choice for many manufactures and for many modern technologies to get to the market and get to patients."

Deemphasizing, But Not Removing Predicates

Criticizing the idea of having to compare devices to predicates, in many ways an idiosyncrasy of the US system, has been a part of device regulatory debate for many years, and discussion has accelerated in recent years. (Also see "*Scrutinizing Substantial Equivalence: 510(k) Predicate Standard Questioned At FDLI*" - Medtech Insight, 22 Apr, 2015.) FDA, and industry, have generally come to the defense of the 510(k) program as it stands, and continue to make the case that the current system puts safe and effective devices on the market.

The agency has been wary of pushing for any fundamental changes to the substantial equivalence model, which would require congressional action. But this new approach in the works appears to provide the option for an end run around some of the shortcomings of the predicate system without an act of Congress.

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The pending policy will require a 510(k)-device sponsor to *identify* a predicate device with the same intended use. Low- or moderate-risk products that don't feasibly fit into established class I or II device categories would have to leverage the *de novo* process. But if a company identifies a predicate, then, it might be possible to leave it there – the sponsor can conduct testing outlined in an FDA guidance or an FDA-recognized consensus standard, and never have to go through the "machinations," as Shuren describes it, of comparing technological characteristics.

The approach only works for device categories that FDA agrees have objective performance and safety criteria in place. There are certain product types that should readily be able to take advantage of this route right off the bat, Shuren says. For instance, he points to *in vitro* diagnostics where clear positive and negative predictive values have been established.

On top of that, the center director expects the pathway itself to trigger a process that fuels its expansion. "Because of the establishment of the program, we anticipate that there will be interest in folks working together to establish criteria where they may not yet exist, so going through data that is already out there, and looking at [how] modern technologies perform, as opposed to looking at older technologies," Shuren noted. "This will drive efforts at FDA through a public process to work to establish objective criteria, as well as, I think, spur the standards development organizations to develop standards or bake in to standards more objective criteria."

It's also likely, he explains, that a natural cycle will develop for new, moderate-risk technology, where the first product in a category enters the market via a *de novo* classification. Subsequent near-term products, developed before agreed-upon objective criteria are available, will enter the market by proving substantial equivalence to the original predicate. Shuren said "with more experience, we would be in a position to establish those objective performance criteria, and then the alternative 510k pathway would be available."

This approach does not mean that the predicate system will be going away any time soon, but its possible things could eventually move in the direction of objective criteria replacing predicates outright, Shuren suggested. "We will have to see down the road if it is a viable approach," he said. "It certainly may turn out that way, but to do so might require change in the law."

Regardless, Shuren positions the alternative pathway as a modernized 510(k) pathway, as the original device regulations get older.

With this nascent approach, he states, "You can really say, this isn't your grandmother's device and it isn't your grandmother's standard."

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