Navigating the U.S. FDA regulatory clearance for digital medical devices: the 510(k) and Pre-Cert program

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Consumer demand for digital health care devices has soared, and it shows no signs of slowing down. But when bringing these devices to market, companies in the digital health space are confronted with numerous challenges. One of the most formidable is ensuring that their product and its updates comply with U.S. Food and Drug Administration (FDA) regulations, and that may mean navigating a lengthy clearance process. In 2017, however, the FDA introduced its Pre-Cert program, which is designed to fast-track clearance of a certified company's current — and future — digital medical devices if the company proves it has the culture, capabilities, and transparency to meet the FDA's quality and safety standards. Nine companies are participating in a Pre-Cert pilot, while the industry awaits the next phase.

In this hoganlovells.com interview, Kristin Zielinski Duggan, a Hogan Lovells counsel in Washington, D.C., discusses the FDA's clearance process for digital medical devices and what companies can do to help streamline it. She also suggests that communications, software, and other companies seeking clearance for their devices start with one basic question: does my product fit the definition of an actively regulated digital medical device?

What common challenges do companies face related to compliance with FDA regulations and getting clearance of their digital medical devices?

Kristin Zielinski Duggan: The first thing that companies have to think about is whether they're offering a medical device or not. There are so many mobile apps out there that are either not devices, or fall under what is called enforcement discretion, where the FDA is not actively regulating them. So the first question is always, am I an actively regulated device? There are guidance documents and policy statements constantly coming out — the 21st Century Cures Act made some changes — so it's a moving target.

For things that are not medical devices, or that are carved out of active medical device regulation, companies don't have to do a tremendous amount, from an FDA perspective. But companies that make something that fits the definition of a device and does not fit in any of these exceptions is going to be actively regulated by FDA. So if it's intended to help prevent or

treat or diagnose a disease, and it doesn't fit in one of these categories, then FDA is going to want to know about it.

If your product is a digital health care device, one of the challenges for a lot of companies is that they are actually telecommunications, Internet, technology, or software companies — not a traditional medical device manufacturer. So they essentially get turned into a medical device company, which comes with a tremendous amount of regulation and responsibility that you don't have if you're not a medical device company.

What mistakes do these companies often make when they have something that is a medical device but they're not accustomed to the clearances and compliance process?

Zielinski Duggan: One of the things we see all the time with software-type products is that, if you're a medical device, you have to very tightly control the changes you make to your product. You have to assess each and every change for whether it requires additional FDA clearances. A lot of software companies struggle with or don't fully understand that. They have software teams that are used to making tweaks on a daily or very regular basis to fix or make something better, and they don't always realize what implications those types of things have from an FDA perspective. So they may not be actually controlling the changes in the way that FDA would expect them to.

What are some of the ways in which we help clients understand these nuances?

Zielinski Duggan: With regard to making changes, that is one part of what is called the quality system, from an FDA perspective. It governs the entire process of what you should be doing — from how your management is structured, to your standard operating procedures. There's less manufacturing controls having to do with software, but there are controls you have to put in place for any suppliers that you have. Complying with the quality system is something that is really foreign to some companies, and again, assessing changes falls into one bucket of that. But, especially if a company is not a medical device company, the whole thing can be difficult. We frequently help clients assess the changes to their products to see whether they require additional clearances.

We also frequently help clients with the initial clearance. There are all sorts of different avenues to get a product on the market. Generally today they go through what's called the 510(k) program and get cleared by FDA.

How do you help companies going through the FDA's 510(k) program?

Zielinski Duggan: One big thing that our group does is help clients get medical devices approved or cleared. Companies that have a product that falls under an actively regulated device classification sometimes have to go through the 510(k) program, which means they have to get agency clearance before they can market their product. That's a process that can take many months, which again is always a challenge for software companies, as they don't understand why FDA can't just move quickly like they do in terms of development and updating the software. We help them navigate that process.

We probably do hundreds of 510(k)s a year and know all the different groups at FDA. There are different divisions and branches within those divisions that have different personalities and requirements in terms of testing. A digital health device is classified by therapeutic area — ob/gyn, cardiology, or whatever disease the device is related to. It could be within any of these groups at FDA; there's not a particular group that reviews only digital health devices. We're familiar with that process and what the agency is typically looking for.

The best way to navigate that process and get through it unscathed, as quickly as possible, and with a successful outcome, oftentimes involves going to meet with FDA beforehand to get an even better idea of what the agency wants. That can sometimes seem to companies like it would extend the process, but in fact it often results in a faster process, because once you file your marketing submission to FDA, it moves through a lot quicker. We help people with that process, called the pre-submission program, as well.

The FDA developed a new Pre-Cert, or Precertification, program. How does it work?

Zielinski Duggan: As of now, digital health products that are determined to be actively regulated medical devices are going through the traditional pathways at FDA. There's nothing all that different from that standpoint — you still have to prove exactly the same thing that you have to prove for a hardware type of medical device.

But FDA has rolled out what they're calling the Precertification pilot program; it's really more in an information-gathering stage now than a pilot. They're trying to flip the way they do everything because of the digital health revolution and the fact that there are just so many digital products and apps, and they change so quickly, FDA just can't keep up with them. The FDA has admitted that it doesn't work in the current regulatory framework.

As an example, if somebody today had a digital health product that was a medical device that was cleared through the 510(k) process, and they make a change to it that would require a new 510(k), they may view that change like a software update that can be made in a day. But if that has to go back to FDA — that could be another three to six months before they can make the change. For companies that are working on software products, that's just not feasible.

So the FDA has put out this concept called the Pre-Cert program. What they're planning on doing

really flips the regulatory paradigm on its head: they're essentially certifying a company as opposed to a product.

Currently, you submit an application for a product and they review it and clear that product. What they're talking about doing is certifying a company as a quality company. There would be several levels of that; they're envisioning two. Then that company would have either some sort of exemption or a streamlined process for their product in order to be able to market it. Essentially the idea is to say that your company is a quality company because the way that you develop and test your software has been determined to be up to a certain standard, and you'll get a streamlined process for your new and upcoming products as a result.

The companies in the pilot program are Apple, Fitbit, Johnson & Johnson, Pear Therapeutics, Phosphorous, Roche, Samsung, Tidepool, and Verily. FDA has stated they'll be adding more. But it is not yet in the real pilot stage; right now, they're mainly gathering information.

So it will be very interesting to see what happens with this. There are questions about whether Congress needs to give them additional regulatory authority or whether they can work within the existing framework. There are all kinds of questions about how to implement this program. FDA doesn't know themselves. They've put out what they call working models — including lists of questions they want feedback on — and are soliciting advice. It's a huge challenge, and so different from the way that they operate now that they're really open to feedback from the industry or whoever can help them develop this innovative program.

You've also mentioned another challenge for these companies, which may involve collecting massive amounts of data.

Zielinski Duggan: Yes, and this feeds into the Pre-Cert program. The FDA wants to collect real-world data on what's happening with devices of all types. But as part of the Pre-Cert program, they want data to be collected from the connected digital health devices out there. It's not exactly clear how it's going to work; if a company has 25,000 people that have downloaded their app, how should they be monitoring data on all of those people and feeding that back into their quality system? There's a question as to whether FDA wants all of that information or what they're supposed to be doing with that.

But the idea that they should be monitoring devices out there has come up and the scope is not entirely defined. For other types of medical devices — say, a knee implant — if something bad happens, a doctor has to enter it in an FDA database or call somebody and say, this bad thing happened. Whereas with all these connected and digital health devices, the data is just feeding back to the company, so there will be some obligation to monitor what happens and somehow provide information to the FDA about that. Collecting that information might be a way to improve their product or systems or identify some sort of health problem. But how they will do that, especially on such a large scale, is yet to be determined.

About Kristin Zielinski Duggan:

With a background in biology and economics, Kristin Zielinski Duggan provides strategic advice to companies on scientific and U.S. FDA regulatory challenges, while always keeping business needs in mind. For the past 20 years, she has been counseling cutting-edge companies regarding the development and regulation of medical devices, pharmaceuticals, and combination products.

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