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FDA Publishes Q&A On Precertification Pilot Program For Software Developers

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On September 1, the Food and Drug Administration (FDA) will launch a precertification pilot program for software developers, but has limited the pilot to nine companies. Under this unique program, the FDA may certify companies that develop software which satisfies the definition of a medical device under the Food, Drug and Cosmetic Act (FDCA), rather than clear or approve the companies' individual products before they are marketed. In advance of the pre-cert launch, the FDA released a brief question and answer document discussing the program. The FDA also published a Federal Register notice describing the program in late July.

According to the Federal Register notice, the pilot program "will help inform the development of the Pre-Cert program for software developers, including what criteria can be used to assess whether a company consistently and reliably engages in high-quality software design and testing (validation) and ongoing maintenance of its software products." The FDA stated that it "intends to establish a process for company precertification that could replace the need for a premarket submission for certain products or allow for decreased submission content and/or faster review of marketing submissions for other products."

The Q&A notes the program is seeking companies that have developed, or are in the process of developing, products that meet the statutory definition of a medical device and, in particular, software as a medical device (SaMD). It quotes the International Medical Device Regulators Forum (IMDRF) definition of SaMD as "software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device."

The Q&A is vague on the timing of the precert program. The FDA says it does not know how long the program will last, how much time a participant will have to invest, or how long it will take a particular company to be precertified. It encourages companies who are in, or ready for, the 510(k) process for a particular product to pursue it rather than the precert program.

Curiously, the Q&A states that it is open to startup companies. Given that the selection criteria include: "[T]he company has an existing track record in developing, testing, and maintaining software products demonstrating a culture of quality and organizational excellence measured and tracked by Key Performance Indicators (KPIs) or other similar measures," it seems unlikely a company that has not yet brought a product to market will be selected.

Both the Federal Register notice and the Q&A discuss the information that should be included in a company's statement of interest in the

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program. The FDA is currently accepting statements of interest and there is no submission deadline for the statements, although the program will be limited to nine companies and time may be of the essence.

Companies that want to know more about the pilot program may wish to review the transcript and slides from the FDA's webinar.

For more information, please contact the Barnes & Thornburg LLP attorney with whom you work or the chair of the firm's Food, Drug & Device Group, Lynn Tyler at (317) 231-7392 or lynn.tyler@btlaw.com.

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