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XaTek Inc. receives key FDA designation to aid commercialization of its ClotChip device

SCOTT SUTTELL  



XaTec's ClotChip has earned the FDA's Breakthrough Device designation.

XATEC

The clinical-stage diagnostic device company based in Cleveland said it has received Breakthrough Device designation from the U.S. Food and Drug Administration for ClotChip, a handheld system that can quickly assess the clotting ability of a person's blood.

This article was updated at 1:20 p.m. on Tuesday, March 3, to include a comment from XaTek CEO John Zak.

XaTek Inc., a clinical-stage diagnostic device company based in Cleveland, **said** it has received Breakthrough Device designation from the **U.S. Food and Drug Administration** for

its **ClotChip** technology.

The designation represents "a significant and distinguishing step in advancing" the portable blood-clotting sensor toward commercialization, XaTech said in a **news release** issued Tuesday, March 3. The FDA created the **Breakthrough Devices Program** in 2018 to speed up the development, assessment and review of technologies that "provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions."

XeTek said in its release that ClotChip "measures a patient's bleeding risk profile at bedside from a single drop of blood obtained from a fingerstick, much like a glucometer measures a patient's blood-glucose level." Such immediate notice "can be a critical step in saving the life of someone who may otherwise die from excessive bleeding or clotting," according to the release.

In a statement included in the release, John Zak, XaTek's co-founder and CEO, said, "Once commercially available, this device will fulfill a critical and unmet clinical need for the newer generation of drug therapies known as 'direct oral anti-coagulants' – for which there is no point-of-care test available today."

Zak said in a phone interview on Tuesday afternoon that the company has a Pivotal Clinical Trial set to begin enrollment this summer. The trial, with sites in both the United States and Canada, is expected to take 8-10 months, Zak said, after which, he added, XaTech hopes to be able to use the regulatory pathway to commercialization "optimistically, before the end of 2021."

XaTek said in the release that it "intends to pursue additional indications for use in the near future, potentially including patients on other anti-coagulant therapies, those with hemophilia and other rare bleeding conditions and those with trauma-related indications."

The company in July 2018 **raised \$9.1 million in Series A capital** to advance and test the ClotChip device.

Case Western Reserve's Technology Transfer Office granted an exclusive license in 2016 to XaTek to develop the technology for commercial use.