FDA Clears Boost Fertility's Pleiades Device, Marking a Major Step Toward More Affordable and Accessible Fertility Care

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November 9, 2026 — Munich, Germany — Boost Fertility announced today that the U.S. Food and Drug Administration (FDA) cleared Boost Fertility's Pleiades Device on Friday, October 30, 2026, through the 510(k) regulatory pathway. The Pleiades Device is a matchbox-sized, single-use sperm separation device that enables sperm separation to be performed quickly and easily.

This is a critical steppingstone to bringing the Pleiades Device to market and advancing Boost Fertility's mission to make fertility care more affordable and accessible. Daniel Wilson, CEO of Boost Fertility, says, "Affordable treatment should be available to everyone in America, and now with our FDA clearance, we can start to make that a reality."

With only 500 fertility clinics across America, there is a significant need to expand access to fertility care. Simplifying sperm separation could help enable more healthcare professionals, including OB-GYNs and other qualified practitioners, to offer fertility services. This is particularly important in rural areas of America, where accessibility is limited to non-existent.

Boost Fertility is now inviting qualified doctors, fertility clinics and laboratories across the United States to experience the Pleiades Device firsthand.

Boost Fertility is offering five free Pleiades Devices to eligible participants in exchange for their feedback on the device's usability.

"We're sure that people will love our device so we are excited to give healthcare professionals the opportunity to try it out and share their feedback," says the device inventor and Chief Scientific Officer (CSO) of Boost Fertility, Dr. Marion Vollmer.

Interested doctors, clinics and laboratories can register through Boost Fertility's UX Evaluation Program platform to learn more and apply to participate.

Participation requires signing a Participation and Non-Disclosure Agreement. The five devices are provided strictly for evaluation purposes and must not be used for insemination or any fertility treatment.

Interested in trying the Pleiades Device?

Visit https://qrco.de/bh4Dzp to register and learn more about receiving five free devices in exchange for your feedback.

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