Establishment Labs Submits Investigational Device Exemption (IDE) Filing for Prospective Clinical Trial of Motiva Implants

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NEW YORK, August 7, 2017 (GLOBE NEWSWIRE)

Establishment Labs, a global medical device company focused on aesthetic technologies with a strong emphasis on product development and innovation, announced today that it has submitted an Investigational Device Exemption (IDE) filing to the U.S. Food and Drug Administration (FDA) for its Motiva Implants®, the lead product in its portfolio of innovative aesthetic technologies. Upon acceptance, the IDE would enable the Company to initiate a clinical study in the U.S. to assess the safety profile and patient satisfaction of Motiva Implants.

“This is a very significant milestone for Establishment Labs and patient safety, and hopefully the start of many technologies that we can bring to market in the United States,” said Juan José Chacón-Quirós, CEO and founder of Establishment Labs. “Motiva Implants are already sold in over 60 countries worldwide and have been implanted more than 300,000 times over the past seven years. We are confident that a clinical study in the United States will confirm the safety profile we are seeing in all of our markets.”

The IDE submission for this Motiva Implants study proposes a single arm, multi-center study investigating female patients receiving primary breast augmentation, primary breast reconstruction, or revision surgery. Upon acceptance of the IDE, Dr. Caroline Glicksman, a board-certified plastic surgeon in the U.S., has agreed to lead the study as the principal investigator. The results of the study are expected to support a Pre-Market Approval (PMA) submission to the FDA.
“This is a big day for technological improvement in our industry,” said Roberto de Mezerville, VP of Research, Development & Innovation of Establishment Labs. “The science and technology behind Motiva Implants was developed with enhanced patient safety as a priority, and we look forward to demonstrating that a commitment to innovation in this industry can lead to safer and better patient outcomes in both the aesthetics and reconstruction fields.”

About Establishment Labs:
Establishment Labs is a global, privately held, medical technology company with a strong emphasis on innovation that designs, develops, manufactures and markets an innovative product portfolio. Its CE-marked Motiva Implants® line of silicone breast implants (http://www.motivaimplants.com) utilizes ultra-high purity medical-grade silicone and is subject to the strictest quality assurance testing throughout the manufacturing process. Motiva Implants are sold in more than 60 countries worldwide. Puregraft®’s FDA cleared and CE-Marked technology provides plastic surgeons with purified fat for reinjection on the sterile field and is used in hospitals and clinics around the world. Divina® is a proprietary 3D imaging technology for full integration in consultation and surgical planning of unique solutions for breast aesthetics and reconstruction. All manufacturing facilities are fully compliant with both FDA and ISO applicable standards.
Motiva Implants and Divina are registered trademarks of Establishment Labs.