



Establishment Labs Announces Japanese Regulatory Approval and Reimbursement for Motiva Implants and the Motiva Flora Tissue Expander for Use in Post-Mastectomy Reconstruction

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SANTA BARBARA, Calif.--(BUSINESS WIRE)--Nov. 10, 2022-- Establishment Labs Holdings Inc. (Nasdaq: ESTA), a global medical technology company dedicated to improving women's health and wellness, principally in breast aesthetics and reconstruction, today announced Motiva Implants® and the Motiva Flora® tissue expander have been approved for use in Japan by the Pharmaceuticals and Medical Devices Agency (PMDA). The products have also received reimbursement for post-mastectomy reconstruction under the Japanese National Health System. The first reconstruction patient in Japan was successfully treated with Motiva in early November at Nagoya University Hospital.

"Launching Motiva Flora with Motiva Implants in the Japanese market is a significant step in changing the global standard in breast reconstruction," said Juan José Chacón-Quirós, Founder and Chief Executive Officer. "A core mission for Establishment Labs is to develop and commercialize technologies that improve women's health. Providing Japanese women the ability to match tissue expanders and implant surfaces that are backed by scientific and clinical data is another example of that commitment."

The Motiva Flora tissue expander offers several notable innovations, including Establishment Labs' patented SmoothSilk® surface technology as well as a RFID-enabled, non-magnetic integrated port, that offer potential improvements in imaging, treatment, and overall clinical outcomes and patient satisfaction. More than 2.5 million Motiva implants have been used in over 80 countries since commercial launch of the products in 2010.

Motiva Implants and the Motiva Flora tissue expander are currently not approved for commercial distribution in the United States. Motiva Implants are undergoing clinical investigation pursuant to U.S. FDA regulations for investigational medical devices.

About Establishment Labs

Establishment Labs Holdings Inc. is a global medical technology company dedicated to improving women's health and wellness. The company's initial focus is breast health, principally breast aesthetics and reconstruction. Establishment Labs offers a portfolio of advanced silicone gel-filled breast implants, branded as Motiva Implants® that include a number of innovative and patented features designed to deliver improved aesthetic and clinical outcomes. Since commercial launch in 2010, approximately 2.5 million Motiva Implants® have been delivered to plastic surgeons in over 80 countries. The company also offers or has under development a number of related products and technologies, including the Motiva Flora® tissue expander and Mia Femtech™, the company's minimally invasive breast enhancement procedure. In 2018, Establishment Labs received an investigational device exemption (IDE) from the FDA for the Motiva Implant® and began a clinical trial to support regulatory approval in the United States. Motiva Implants® are manufactured at the company's two facilities in Costa Rica, which are compliant with all applicable regulatory standards under ISO13485:2016 and FDA 21 CFR 820 under the MDSAP program. Please visit our website for additional information at www.establishmentlabs.com.

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