



Establishment  
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## Establishment Labs Announces Regulatory Clearances in Brazil

March 31, 2017

**NEW YORK, NY (PRWEB) MARCH 31, 2017**

Establishment Labs, a global medical device company focused on breast surgery technologies with a strong emphasis on product development and innovation, announced today that it has received regulatory approval from the Brazilian National Health Surveillance Agency (ANVISA) to market Motiva Implants® and Puregraft®.

According to a survey by the International Society of Aesthetic Plastic Surgery (ISAPS), there were over 166,000 breast augmentation procedures performed in Brazil in 2015, the world's second largest market after the United States. Having more than 5,500 board certified plastic surgeons, Brazil is also one of the largest markets for fat grafting with more than 110,000 procedures performed in face, breast and body contouring in 2015.

"Regulatory clearance to market Motiva Implants® and Puregraft® in Brazil is an exciting milestone for Establishment Labs," said Juan José Chacón Quirós, Chief Executive Officer of Establishment Labs, "Brazilian surgeon interest and support has been very high pre-launch, and we've seen enough demand to validate our commercialization strategy for Motiva Implants® and Puregraft® through our own direct sales network. This commitment to Brazil should position our company as a leader in the Brazilian market."

Establishment Labs had already received the GMP (Good Manufacturing Practices) certification from Brazil's National Health Surveillance Agency (ANVISA) following an inspection and audit of its manufacturing facility in San José, Costa Rica. Brazil's GMP regulations, which closely resemble the internationally recognized ISO 13485 standard, require medical device manufacturers to have a quality system for the design, manufacture, packaging, labeling and storage of their products. "We are pleased with the successful completion of the ANVISA clearance for our products and GMP certification, which is evidence of our commitment to produce innovative products in strict adherence to our quality system," said Salvador Dada, Chief Operating Officer of Establishment Labs.

According to Eddie de Oliveira, Vice-President of Sales for Latin America, "We are honored to begin our sales efforts in one of the most dynamic aesthetic markets in the world. The Brazilian plastic surgeon is known for their skill, expertise and innovative surgical techniques. We hope to win their confidence with our advanced line of surgical products."

### About Establishment Labs:

Establishment Labs is a global, privately held, breast implant and medical technology company that designs, develops, manufactures and markets an innovative product portfolio consisting of advanced silicone-filled breast and body shaping implants (<http://www.motivaimplants.com>). Its CE-marked Motiva Implants® line of silicone breast implants utilizes medical-grade silicone and is subject to rigorous 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. The Puregraft® technology is used in hospitals and clinics around the world and provides physicians with confidence and convenience in fat grafting surgical procedures.