

Implantica announces Module 1 is accepted and closed by FDA in the PMA application for RefluxStop™

Implantica AG (publ.), a medtech company at the forefront of introducing advanced technology into the body, including a unique device RefluxStop™ for the treatment of acid reflux, a treatment field with 1 billion sufferers, is pleased to announce that the FDA has accepted Module 1 of the company's premarket approval (PMA) application, and that this module is now considered closed.

Module 1 contained the quality systems and manufacturing information for RefluxStop™, including the production and packaging information. FDA's review has been completed in full and the quality systems/manufacturing module is now considered closed by FDA. Prior to formal PMA approval of RefluxStop™, FDA will perform a pre-approval inspection of the production sites to ensure the RefluxStop™ manufacturing facilities, methods, and controls are in compliance with the applicable requirements of the Quality System regulation (21 CFR part 820).

Implantica's founder, CEO, and inventor of RefluxStop, Dr. Peter Forsell says, "We are grateful to FDA for their substantive review and acceptance of our Module 1 submission. We look forward to receiving FDA's feedback on Module 2, which is expected in the very near-term and is – from our perspective – the absolutely key module that includes the remarkable 5-year Clinical study outcomes of RefluxStop™."

For further information, please contact:

Nicole Pehrsson, Chief Corporate Affairs Officer
Telephone (CH): +41 (0)79 335 09 49
nicole.pehrsson@implantica.com

Implantica is listed on Nasdaq First North Premier Growth Market in Stockholm.

The company's Certified Adviser is FNCA Sweden AB, info@fnca.se

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About Implantica

Implantica is a medtech group dedicated to bringing advanced technology into the body. Implantica's lead product, RefluxStop™, is a CE-marked implant for the prevention of gastroesophageal reflux that will potentially create a paradigm shift in anti-reflux treatment as supported by successful clinical trial results. Implantica also focuses on eHealth inside the body and has developed a broad, patent protected, product pipeline based partly on two platform technologies: an eHealth platform designed to monitor a broad range of health parameters, control treatment from inside the body and communicate to the caregiver on distance and a wireless energizing platform designed to power remote-controlled implants wirelessly through intact skin. Implantica is listed on Nasdaq First North Premier Growth Market (ticker: IMP A SDB). Visit www.implantica.com for further information.

About RefluxStop™

RefluxStop™ is a new innovative treatment that has the potential to spur a paradigm shift in anti-reflux surgery. It's unique mechanism of action differentiates it from standard of care and current surgical solutions. Longer established surgical options for GORD involve encircling the food passageway to support the lower oesophageal sphincter's closing mechanism and are commonly associated with side effects such as swallowing difficulties, pain when swallowing and inability to belch and/or vomit.

In contrast, the RefluxStop™ device treats the cause of acid reflux without encircling and putting pressure on the food passageway. It restores and maintains the lower oesophageal sphincter in its original, natural position.

The RefluxStop™ mechanism of action is focused on reconstructing all three components of the anti-reflux barrier, that if compromised could possibly result in acid reflux. It restores and supports the natural anatomical physiology of the body allowing the body to itself solve the problem with acid reflux.

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Media Contact:

Implantica AG

Juanita Eberhart, VP Marketing & Advocacy

M: +1 925-381-4581

juanita.eberhart@implantica.com