

Implantica announces positive feedback received from U.S. FDA of the RefluxStop™ PMA Module 2 submission

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, announces that U.S. FDA has completed its review of the PMA Module 2 submission and provided its feedback, in which the company sees no barrier for responding.

FDA has completed its review of the company's second modular submission of its PMA, which contained the Clinical Data, Usability Testing, and Labeling information supporting RefluxStop™. FDA has provided Implantica with its written feedback on the content submitted, all of which the company considers to be minor. A response strategy has been identified for the questions raised, and the company sees no impediment to the overall PMA approval process based on FDA's Module 2 feedback. Responses to the Module 2 feedback will be submitted in conjunction with the final Module 3 submission in the near term.

Dr. Peter Forsell, Implantica's founder, CEO, and the inventor of RefluxStop, says, "We are thankful for FDA for their review of Module 2 and are pleased to receive their positive feedback on our submission thus far. Module 2 includes the results of the RefluxStop™ clinical study and is by far the most important module for this PMA from our perspective. The 5-year outcomes in conjunction with data reported in the literature are extremely positive and indicate that RefluxStop™ may revolutionize this treatment field. Implantica will, in the near term, submit the last component of our PMA application (Module 3) and work with FDA to bring RefluxStop™ to the U.S. market as soon as possible."

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

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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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