

Implantica announces continuing progress in modular PMA application to FDA 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, announces that the Module 1 review of the company's FDA premarket approval application (PMA) submission is progressing as expected.

Upon completion of its review of Module 1, the first of three modules to be submitted in our PMA, FDA provided Implantica a list of deficiencies, all of which the company considers to be minor. No major issues have been identified by FDA thus far, and Implantica is in the process of addressing these comments. Based on FDA's response, the company has decided to submit Module 2 of our PMA application once our response to FDA's findings on Module 1 has been finalized.

Based on this approach, the company does not anticipate any significant impact on the overall timeline. Implantica will provide an update within the next 1-2 months.

Implantica's CEO, Dr. Peter Forsell says, "We are passionate about the progress of our PMA submission to FDA and are pleased with the positive feedback received on our Module 1 submission. We are excited to announce that the 5-year results to be submitted in Module 2 are remarkable and consistent with the positive outcomes observed at the 1-4-year marks, which is truly rewarding."

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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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