



Implantica submits U.S. FDA Premarket Approval (PMA) application for RefluxStop® (first module)

Implantica AG (publ.), a medtech company at the forefront of bringing advanced technology into the body, announces the submission of the first module of the PMA application to the U.S. FDA for RefluxStop®, an innovative device for the treatment of Gastroesophageal Reflux Disease (GERD).

The U.S. FDA has agreed to a modular submission process for the RefluxStop PMA application. This process provides for ongoing review and feedback from the FDA as the modules are submitted. The second and third (final) modules are anticipated to be submitted to the FDA in three-month intervals later this year.

An estimated 27% of the adult population in the U.S. struggle with GERD¹ and 40% of GERD patients don't respond to PPIs, the most common medication to treat the disease.² This leaves tens of millions of patients with limited options to treat the relentless, painful symptoms of GERD. Even worse, in the U.S. and EU, around 48,000 people die annually from esophageal adenocarcinoma, with strong indications in the literature to be caused by acid reflux.

Dr. Peter Forsell, CEO of Implantica, says, "This FDA filing is a key fundamental milestone for RefluxStop®³ and puts us in motion for the U.S. launch preparation ahead of the pending FDA approval. The basis for this expedited submission is the extraordinary 5-year clinical results from the RefluxStop CE mark study. Furthermore, more than 750 patients have been treated with the RefluxStop procedure in Europe, and the clinical outcome during the commercialization process has been in line with the CE study results."

Dr. Forsell continues, "The broader interest and acceptance for RefluxStop has been phenomenal so far and continues to grow rapidly among the leading European surgeons and Reflux centers of excellence, driven by exceptional patient outcomes and the larger medical community's support. With the recently announced completion of the US Human Factors study, a crucial milestone for PMA application, we are gearing up to file the next FDA module in three months time and are looking forward to bringing RefluxStop® to the U.S. market."

Reference:

1. Antunes C, Aleem A, Curtis SA. Gastroesophageal Reflux Disease. [Updated 2023 Jul 3]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. Available from: <http://www.ncbi.nlm.nih.gov/books/NBK441938/>

2. Kahrilas PJ, Boeckxstaens G, Smout AJ. Management of the patient with incomplete response to PPI therapy. *Best Pract Res Clin Gastroenterol.* 2013 Jun;27(3):401-14. doi: 10.1016/j.bpg.2013.06.005. PMID: 23998978; PMCID: PMC3761380.

3. RefluxStop® is a registered trademark in the U.S.

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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. Its unique mechanism of action differentiates it from standard of care and current surgical solutions. Longer established surgical options for GERD involve encircling the food passageway to support the lower esophageal 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 esophageal 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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