

# Implantica submits the last and final module 3 of the FDA PMA Application for RefluxStop® for US market approval

**Implantica AG (publ.), a MedTech company at the forefront of introducing advanced technology into the body, including the unique device RefluxStop® for the treatment of acid reflux, a treatment field with 1 billion sufferers, announces the submission of the third and final module of the RefluxStop® pre-market approval (PMA) application with the US Food and Drug Administration (FDA), along with responses to the second module.**

Implantica submitted the last and final Module 3 of the RefluxStop® PMA application together with the response to Module 2 review findings to FDA yesterday. Module 2, the clinical module, primarily addressed what we believed were minor findings. Module 3 is focused on tests of the product such as bench testing and biocompatibility testing for the RefluxStop® device.

In line with the positive feedback in the FDA PMA application process so far, the latest RefluxStop® data submitted as part of the Module 2 response, as well as in the final Module 3, is quite robust and conclusive in Implantica's opinion. We hope the newly submitted data and responses will not only continue to meet the stringent requirements for the PMA approval process but also exceed them. The continued process relies to a large extent now on FDA, which will guide Implantica in the coming steps. FDA's feedback on Module 3 is expected sometime in the autumn.

Inventor of RefluxStop®, Founder and CEO of Implantica, Dr. Peter Forsell, says, "I want to extend my gratitude to U.S. FDA for this thorough evaluation process of every facet of a new technology, such as RefluxStop®. Now more than ever, I believe we are on the cusp of a new generation of much needed surgical solutions for GERD with the potential to transform the standard of care for GERD patients in the U.S.."

Dr Forsell continues, "This is a significant milestone for Implantica, one we all waited for. Undoubtedly, GERD is a grave and growing issue in the U.S. today, impacting approximately 22-27% of adults in the U.S. population. With over 1300 patients treated across nearly 50 centers in Europe and excellent long-term 5-year data results from the pivotal study, I believe RefluxStop® is poised to help these hugely underserved patients in the U.S. and worldwide in the years to come!"

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. Harsányi, L., Kincses, Z., Zehetner, J. et al. Treating acid reflux without compressing the food passageway: 4-year safety and clinical outcomes with the RefluxStop device in a prospective multicenter study. *Surg Endosc* 38, 6060–6069 (2024). <http://doi.org/10.1007/s00464-024-11114-0>

4. Shih-Chi Ho et al., Ineffective esophageal motility is a primary motility disorder in gastroesophageal reflux disease. Digestive Diseases and Sciences, 2002. 47(3): 652-6

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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](http://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 GORD 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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