

Implantica submits final response to FDA in the PMA application for RefluxStop® for U.S. market approval

Implantica AG (publ.), a medtech company at the forefront of introducing advanced technology into the body, including the innovative RefluxStop® device for the treatment of acid reflux, a treatment field with 1 billion sufferers, announces that it has submitted its final response to the U.S. Food and Drug Administration (FDA) feedback regarding Module 3 of the Premarket Approval (PMA) application for RefluxStop®.

The submission includes Implantica's responses to FDA's remaining questions and requests, including the completion of additional testing requested by the Agency following the previously announced 100-Day Meeting, review of all three PMA modules, and multiple pre-approval inspections conducted by FDA. The six preapproval inspections, including manufacturing sites, Quality System, and BIMO (clinical trial inspections), were all successfully concluded as reported in the closing meetings.

Dr. Peter Forsell, founder, CEO, and inventor of RefluxStop®, says, "The submission of our final response to FDA marks a major milestone for Implantica and reflects many years of extensive clinical, scientific, regulatory, and operational work. We are grateful for FDA's thorough and constructive review throughout this process."

Dr. Forsell continues, "RefluxStop® has all the attributes to transform the surgical treatment of GERD in the United States. The strong and growing interest we continue to see from leading surgeons and gastroenterologists, together with the excellent long-term clinical outcomes demonstrated across multiple studies and real-world patient populations, further strengthens our confidence in the future potential of RefluxStop®. We now look forward to the completion of the PMA review process and bringing RefluxStop® to patients in the U.S., pending FDA approval."

RefluxStop® is a unique surgical treatment for gastroesophageal reflux disease (GERD) designed to restore the natural anatomy of the body without compressing the food passageway. The PMA application is supported by extensive long-term clinical data, including the company's pivotal clinical study with the 5-year follow-up requested by FDA, the results of which have been published in two peer-reviewed scientific papers demonstrating excellent long-term safety and efficacy outcomes for RefluxStop®.

For further information, please contact:

Nicole Pehrsson, Chief Corporate Affairs Officer
Telephone (CH): +41 (0)43 505 20 57
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

The information was sent for publication, through the agency of the contact person set out above, on May 20, 2026, at 08:00 a.m. (CEST).

About Implantica

Implantica is a medtech company focused on bringing advanced implantable technologies into the body to improve patient outcomes and quality of life. The company's lead product, RefluxStop®, is a CE-marked implant for the treatment of gastroesophageal reflux disease (GERD) with the potential to transform the standard of care in anti-reflux surgery, supported by strong long-term clinical outcomes.

In addition to RefluxStop®, Implantica has developed a broad, patent-protected product pipeline partly incorporating two platform technologies: an eHealth platform designed to enable communication with and remote monitoring of implants inside the body, and a wireless energizing platform designed to wirelessly power implantable devices through intact skin. Treatment could be changed remotely, saving cost for society.

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 treatment for GERD designed to address the root cause of acid reflux without compressing the food passageway.

Unlike conventional anti-reflux surgical procedures, which typically rely on encircling the esophagus and are often associated with side effects such as swallowing difficulties, inability to belch or vomit, and gas bloating, RefluxStop® restores and maintains the lower esophageal sphincter in its natural anatomical position.

The unique mechanism of action of RefluxStop® is designed to reconstruct the body's natural anti-reflux barrier while preserving normal physiological function, offering the potential for effective reflux control with reduced side effects compared to traditional surgical approaches.

Newsroom

<http://www.implantica.com/media/media-kit>

Community

<http://ch.linkedin.com/company/implantica>

<http://www.twitter.com/implantica>

Media Contact:

Implantica AG

Juanita Eberhart, VP Marketing & Advocacy

M: +1 925-381-4581

juanita.eberhart@implantica.com