

Implantica announces U.S. FDA has provided feedback on the final RefluxStop® PMA submission, Module 3

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 U.S. Food and Drug Administration (FDA) has supplied its review of the final PMA Module 3 submission for RefluxStop® and provided favorable feedback, as assessed by the company.

Dr. Peter Forsell, Implantica's founder, CEO, and the inventor of RefluxStop®, commented:

"FDA has now provided its feedback on the final module of our PMA submission for U.S. market approval to sell RefluxStop® in the U.S. The feedback is positive and can be addressed efficiently in our view. We are meeting with FDA on October 3rd to discuss the best path forward in addressing a few outstanding questions and requests. Depending on the outcome of this meeting, we expect to provide our responses to FDA's feedback within a timeframe ranging from a few weeks to a few months. We are grateful for FDA's thorough and constructive handling of our submission. RefluxStop® has the potential to be a true game-changer for the many tens of millions of Americans suffering from severe acid reflux."

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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 GERD 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 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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