

# Implantica completes FDA 100-Day Meeting for RefluxStop® PMA application

**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 over 1 billion sufferers, announces the successful completion of its 100-Day meeting with the U.S. Food and Drug Administration (FDA) regarding the Premarket Approval (PMA) application for RefluxStop®.**

The 100-Day meeting represents a key milestone in the FDA's PMA review process, providing an opportunity for the company and the FDA review team to discuss preliminary findings of the submission, clarify outstanding questions, and confirm the pathway forward.

Dr. Peter Forsell, CEO and founder of Implantica, says, "We are very encouraged by the constructive outcome of the FDA 100-Day meeting. The dialogue provided valuable clarity on what FDA requires in the remaining steps in the PMA review process. With this feedback, Implantica now has the necessary insight to finalize the remaining pieces of information that FDA would like to see."

Dr. Forsell continues, "The PMA process is a large and complex undertaking, and Implantica believes we are now close to the finish line. The FDA will conduct audits of one hospital site, the Implantica site, and two of the production facilities during October and November, meanwhile in parallel some additional testing required by FDA is performed. A final decision by FDA is expected at the latest 92 days after our responses are received by the Agency."

**For further information, please contact:**

Nicole Pehrsson, Chief Corporate Affairs Officer

Telephone (CH): +41 (0)79 335 09 49

[nicole.pehrsson@implantica.com](mailto: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](mailto:info@fnca.se)

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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. 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 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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### **Media Contact:**

Implantica AG

Juanita Eberhart, VP Marketing & Advocacy

M: +1 925-381-4581

[juanita.eberhart@implantica.com](mailto:juanita.eberhart@implantica.com)