

Implantica files pre-submission with FDA for RefluxStop™

Implantica AG (publ) today announced it has completed a pre-submission to the U.S. Food and Drug Administration (FDA) for RefluxStop™, a CE-marked medical implant for the prevention of gastroesophageal reflux disease (GERD).

Implantica expects to receive an initial meeting with the FDA within 75-90 days of the pre-submission filing date, at which point the company will have a better understanding of the path forward for FDA approval.

“Our pre-submission is the next step in terms of FDA approval for RefluxStop™ which has the potential to totally change acid reflux treatment. Gastroesophageal reflux disease is a highly prevalent condition, affecting approximately 20 percent of the US and 17 percent of the European population weekly,” said Dr. Peter Forsell, CEO of Implantica.

In addition to causing much discomfort and pain, acid reflux can also lead to serious consequences with 10-20 percent of daily sufferers developing pre-cancerous changes in the lower esophagus, so-called Barrett’s esophagus, as a result of stomach acid repeatedly coming in contact with the lining of the esophagus. Current surgical acid reflux treatments function by compressing the food passageway, often causing several unnecessary complications. RefluxStop™ has a completely different design principle, which according to Implantica’s clinical investigation achieves better results without the complications associated with existing surgical treatments.

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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 energising 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.