

# Implantica takes a big step forward in its RefluxStop™ U.S. approval process discussions with FDA

Implantica AG (publ) today announces feedback from its third pre-submission meeting with the U.S. Food and Drug Administration (FDA) for the approval of RefluxStop™. FDA indicated its willingness to accept a Premarket Approval (PMA) submission for review based solely on the existing long-term European data for RefluxStop™, which if approved, would allow for U.S. market entry without a premarket U.S. clinical trial.

Implantica received helpful feedback from the FDA in its recent supplemental pre-submission meeting where the regulatory pathway of RefluxStop™ was discussed. Due to the favorable clinical investigation results of RefluxStop™, FDA has agreed to receive a PMA marketing application based on existing European clinical data alone. Implantica will provide the FDA with additional longer-term safety and efficacy data from its ongoing European clinical investigation at 4.5 year follow-up and thereafter file a PMA marketing application. The company looks forward to cooperating with the FDA and appreciates their support thus far.

“The situation for acid reflux sufferers is very unsatisfactory today with drug treatment potentially causing many long-term serious side effects and existing surgical methods are simply not good enough, causing complications and discomfort. The worst is that 48’000 people die annually from esophageal adenocarcinoma in the U.S. and EU alone since repetitive reflux of acid into the lower esophagus causes cancer, and most of these deaths are caused by acid reflux,” said Peter Forsell, CEO of Implantica.

“We are very appreciative of the FDA’s willingness to consider our existing European clinical data for regulatory approval in the U.S. and from my standpoint, as a surgeon in this field, the biggest winner will be the patients,” said Peter Forsell, CEO of Implantica.

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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](http://www.implantica.com) for further information.