August 20, 2026

Implantica CE Reflux Ltd.
Melanie Houselog
Sr. Director & Head of Global Quality & Regulatory Affairs
Sir Temi Zammit Buildings, Malta Life Sciences Park
San Gwann, SGN3000
Malta

Re: P250018
Trade/Device Name: RefluxStop® Device and RefluxStop® Deployment Tool
Product Code: LEI
Filed: June 23, 2025
Amended: May 20, 2026

Dear Melanie Houselog:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the RefluxStop® Device and RefluxStop® Deployment Tool. This device is indicated for:

RefluxStop is an implantable sterile medical device intended to treat acid and non-acid reflux in patients diagnosed with gastroesophageal reflux disease (GERD). The device ensures maintenance of a normal physiological situation for the gastroesophageal junction (GEJ) in a defined intra-abdominal position, allowing a natural physiological function of the lower esophageal sphincter (LES) thereby reducing or eliminating acid and non-acid reflux.

The RefluxStop Deployment Tool is indicated for patients diagnosed with Gastroesophageal Reflux Disease (GERD), defined by abnormal impedance pH and/or pH testing, and indicated for RefluxStop implantation.

Based upon the information submitted, the PMA is approved. You may begin commercial distribution of the device in accordance with the conditions of approval described below. Although this letter refers to your product as a device, please be aware that some approved products may instead be combination products. The Premarket Approval Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm identifies combination product submissions.

The sale and distribution of this device are restricted to prescription use in accordance with 21 CFR 801.109 and under section 515(d)(1)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (the act). The device is further restricted under section 515(d)(1)(B)(ii) of the act insofar as the labeling must specify the specific training or experience practitioners need in order to use the device. FDA has determined that these restrictions on sale and distribution are necessary to provide reasonable assurance of the safety and effectiveness of the device. Your device is therefore a restricted device subject to the requirements in sections 502(q) and (r) of the act, in addition to all other applicable requirements, including those governing the manufacture, distribution, and marketing of devices.

Expiration dating for RefluxStop® System has been established and approved at five (5) years for the RefluxStop® Device implant and up to 200 cleaning and sterilization cycles of the metal components of the RefluxStop® Deployment Tool and 50 cleaning and sterilization cycles of the silicone component of the RefluxStop® Deployment Tool. This is to advise you that the protocol you used to establish this expiration dating is considered an approved protocol for the purpose of extending the expiration dating as provided by 21 CFR 814.39(a)(7).

Continued approval of the PMA is contingent upon the submission of periodic reports, required under 21 CFR 814.84, at intervals of one year (unless otherwise specified) from the date of approval of the original PMA. This report, identified as "Annual Report" and bearing the applicable PMA reference number, should be submitted to the CDRH Portal. The Annual Report should indicate the beginning and ending date of the period covered by the report and must include the information required by 21 CFR 814.84.

In addition to the above, and in order to provide continued reasonable assurance of the safety and effectiveness of the PMA device, under 21 CFR 814.82(a)(9), the Annual Report must include, separately for each model number (if applicable), the number of devices sold and distributed during the reporting period, including those distributed to distributors. The distribution data will serve as a denominator and provide necessary context for FDA to ascertain the frequency and prevalence of adverse events, as FDA evaluates the continued safety and effectiveness of the device.

In addition to the Annual Report requirements, you must provide the following data in post-approval study (PAS) reports for each PAS listed below.

1. The **REVEAL study** is a post-market study to assess safety and effectiveness of RefluxStop® in the treatment of Gastroesophageal Reflux Disease (GERD) in general hospital practice New Enrollment PAS (Study Number RXI009, Version 7.0, dated July 30, 2026):

   This is a prospective, single-arm, multi-center study designed to evaluate the short- and long-term safety and effectiveness of RefluxStop® in the treatment of GERD. The PAS will enroll a total of 200 patients with hiatal hernia size ≤ 3 cm, who will be implanted with RefluxStop® and followed for 5 years. Study participants will be enrolled at up to 10 clinical sites (minimum of 4 sites), with at least 50% of sites located in the United States and at least half of all procedures conducted at U.S. sites.

   The primary safety endpoint is the incidence of procedure- and device-related serious adverse device effects (SADEs), serious adverse events (SAEs) and device deficiencies (DDs) at 1 year. The rate of

this composite endpoint will be compared to a performance goal (PG) of 16.2%. The primary effectiveness endpoint is pathologic acid in the lower esophagus measured by 24-hour pH monitoring (total percentage of time pH <4) at 1 year.

Secondary study endpoints are as follows. Secondary safety endpoints include: incidence of procedure- and device-related SADEs, SAEs and DDs at all time points excluding at year 1, comprising month 6 as well as years 2 to 5; and incidence of procedure- or device-related Adverse Events (ADEs or AEs) at 6 months and annually thereafter up to 5 years. Secondary effectiveness endpoints include: subjects with <50% improvement of GERD-HRQL since baseline due to GERD; reduction in GERD-HRQL group score, measured at 6 months and years 1 to 5 compared to baseline; regular daily PPI usage due to GERD/acid reflux at 6 months and years 1 to 5; total percentage of time pH <4 measured by 24-hour pH monitoring at year 1; pathologic 24-hour pH monitoring and on-label device position at years 2 to 5; and incidence of inability to belch at 6 months and at years 1 to 5

The main 1-year safety and effectiveness endpoints will be analyzed as follows:

- The incidence of procedure- and device-related SADEs, SAEs and DDs at year 1 (primary safety endpoint) will be compared to a performance goal of <16.2%.

- Proportion of patients having pathologic 24-hour pH monitoring at year 1 (primary effectiveness endpoint) will be compared to a performance goal of 40%.

- Proportion of patients having <50% improvement of GERD-HRQL score at year 1 compared to baseline (secondary effectiveness endpoint) will be compared to a performance goal of <40%.

For each of the three evaluations of 1-year endpoints, a descriptive summary will be provided on the observed rates compared to the defined performance goals.

In addition, a long-term evaluation of device performance will be conducted by comparing 5-year endpoints in the PAS to long-term results following Nissen fundoplication based on literature.

Descriptive analysis will be conducted on all other clinical endpoints.

From the time of study protocol approval (date of this letter), you must meet the following patient enrollment milestones:

- First patient enrolled within 6 months
- 20% of patients enrolled within 12 months
- 50% of patients enrolled within 18 months
- 100% of patients enrolled within 24 months

In addition, you must submit separate periodic reports on the progress of the PAS as follows:

- PAS Progress Reports every six (6) months until patient enrollment has been completed, and annually thereafter from the date of the PMA approval letter, unless otherwise specified by FDA.

- If any enrollment milestones are not met, you must begin submitting quarterly enrollment status reports (i.e., every 3 months), in addition to your periodic (6 month) PAS Progress Reports, until FDA notifies you otherwise.

- Submission of Final Report three (3) months after study completion (i.e., last enrolled patient completes 5-year follow-up)

Each PAS report should be submitted to the CDRH Portal identified as a "PMA Post-Approval Study Report" in accordance with how the study is identified above and bearing the applicable PMA reference number.

Be advised that failure to comply with any post-approval requirement, including the initiation, enrollment, reporting, and completion requirements outlined above, constitutes grounds for FDA withdrawal of approval of the PMA in accordance with 21 CFR 814.82(c) and 814.46(a)(2).

Be advised that the failure to conduct any such study in compliance with the good clinical laboratory practices in 21 CFR part 58 (if a non-clinical study subject to part 58) or the institutional review board regulations in 21 CFR part 56 and the informed consent regulations in 21 CFR part 50 (if a clinical study involving human subjects) may be grounds for FDA withdrawal of approval of the PMA in accordance with 21 CFR 814.46(a)(3)-(4).

Be advised that protocol information, interim and final results will be published on the Post Approval Study Webpage https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma_pas.cfm.

In addition, results from the post approval study should be included in the labeling as these data become available. Any updated labeling must be submitted to FDA in the form of a PMA Supplement. For more information on post-approval studies, see the FDA guidance document entitled, "Procedures for Handling Post-Approval Studies Imposed by PMA Order" (https://www.fda.gov/media/71327/download).

This is a reminder that as of September 24, 2014, class III devices are subject to certain provisions of the final Unique Device Identification (UDI) rule. These provisions include the requirement to provide a UDI on the device label and packages (21 CFR 801.20), format dates on the device label in accordance with 21 CFR 801.18, and submit data to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). Additionally, 21 CFR 814.84 (b)(4) requires PMA annual reports submitted after September 24, 2014, to identify each device identifier currently in use for the subject device, and the device identifiers for devices that have been discontinued since the previous periodic report. It is not necessary to identify any device identifier discontinued prior to December 23, 2013. Combination Products may also be subject to UDI requirements (see 21 CFR 801.30). For more information on these requirements, please see the UDI website available at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-udi-system.

Before making any change affecting the safety or effectiveness of the PMA device, you must submit a PMA supplement or an alternate submission (30-day notice) in accordance with 21 CFR 814.39. All PMA supplements and alternate submissions (30-day notice) must comply with the applicable requirements in 21 CFR 814.39. Additional information about changes that may require a PMA supplement are provided in the FDA guidance document entitled, "Modifications to Devices Subject to Premarket Approval (PMA) - The PMA Supplement Decision-Making Process" https://www.fda.gov/media/81431/download.

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

You are reminded that many FDA requirements govern the manufacture, distribution, and marketing of devices. For example, in accordance with the Medical Device Reporting (MDR) regulation, 21 CFR 803.50 and 21 CFR 803.52 for devices or post-marketing safety reporting (21 CFR Part 4, Subpart B) for combination products, you are required to report adverse events for this device. Manufacturers of medical devices, including in vitro diagnostic devices, are required to report to FDA no later than 30 calendar days after the day they receive or otherwise becomes aware of information, from any source, that reasonably suggests that one of their marketed devices:

1. May have caused or contributed to a death or serious injury; or

2. Has malfunctioned and such device or similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Additional information on MDR, including how, when, and where to report, is available at https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems and on combination product post-marketing safety reporting is available at https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products.

In accordance with the recall requirements specified in 21 CFR 806.10 for devices or the post-marketing safety reporting requirements (21 CFR Part 4, Subpart B) for combination products, you are required to submit a written report to FDA of any correction or removal of this device initiated by you to: (1) reduce a risk to health posed by the device; or (2) remedy a violation of the act caused by the device which may present a risk to health, with certain exceptions specified in 21 CFR 806.10(a)(2). Additional information on recalls is available at https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/industry-guidance-recalls.

CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading. CDRH will notify the public of its decision to approve your PMA by making available, among other information, a summary of the safety and effectiveness data upon which the approval is based. The information can be found at

https://www.fda.gov/medical-devices/device-approvals-denials-and-clearances/pma-approvals. Written requests for this information can also be made to the Food and Drug Administration, Dockets Management Branch, (HFA-305), 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. The written request should include the PMA number or docket number. Within 30 days from the date that this information is placed on the Internet, any interested person may seek review of this decision by submitting a petition for review under section 515(g) of the act and requesting either a hearing or review by an independent advisory committee. FDA may, for good cause, extend this 30-day filing period.

Failure to comply with any post-approval requirement constitutes a ground for withdrawal of approval of a PMA. The introduction or delivery for introduction into interstate commerce of a device that is not in compliance with its conditions of approval is a violation of law.

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with a copy of all final labeling. Final labeling that is identical to the labeling approved in draft form will not routinely be reviewed by FDA staff when accompanied by a cover letter stating that the final labeling is identical to the labeling approved in draft form. If the final labeling is not identical, any changes from the final draft labeling should be highlighted and explained in the amendment.

All required documents should be submitted to the CDRH Portal and should reference the above PMA number to facilitate processing. For more information on the CDRH Portal, please visit https://www.fda.gov/medical-devices/industry-medical-devices/send-and-track-medical-device-premarket-submissions-online-cdrh-portal.

If you have any questions concerning this approval order, please contact Sivakami Venkatachalam at (301) 796-9103 or Sivakami.Venkatachalam@fda.hhs.gov.

Sincerely,

SHANIL P. HAUGEN -S

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