April 16, 2019

BAROnova, Inc.
Lian Cunningham, M.D., Ph.D.
Senior Vice President, Clinical Affairs and Regulatory Affairs
1551 Industrial Road
San Carlos, CA 94070

Re: P180024
Trade/Device Name: TransPyloric Shuttle/TransPyloric Shuttle Delivery Device
Product Code: LTI
Filed: July 9, 2018
Amended: September 6, 2018, and January 17, 2019

Dear Lian Cunningham:

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 TransPyloric Shuttle/TransPyloric Shuttle Delivery Device. This device is indicated for weight reduction in adult patients with obesity with a Body Mass Index (BMI) of 35.0-40.0 kg/m^2 or a BMI of 30.0 to 34.9 kg/m^2 with one or more obesity-related comorbid conditions and is intended to be used in conjunction with a diet and behavior modification program. We are pleased to inform you that 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 located 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 the many other FDA requirements governing the manufacture, distribution, and marketing of devices.

Expiration dating for this device has been established and approved at 6 months.

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 address below. The Annual Report should indicate the beginning and ending date of the period covered by the report and should 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, 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, continued approval of the PMA is based, in part, on your completion of a post-approval study. You are required to do the following:

- enroll your first study subject no later than 6 months after device commercialization (commercialization being when the first device is shipped);
- enroll and treat at least 50 subjects within 12 months of commercialization;
- enroll and treat at least 130 subjects within 18 months of commercialization;
- complete enrollment and treatment of at least 260 subjects within 26 months of commercialization;
- ensure at least 200 subjects reach 12-month completion in the treatment phase of the study by 39 months post-commercialization;
- ensure at least 100 subjects reach 18-month completion in the weight-loss maintenance phase of the study by 46 months post-commercialization;
- and submit a final report to the Agency within 53 months post-commercialization.

You must provide the following data in post-approval study (PAS) reports. A PAS Progress Report must be submitted for this study every six (6) months during the first two (2) years of the study and annually thereafter, unless otherwise specified by FDA. The report, identified as a "PMA Post-Approval Study Report" in accordance with how the study is identified below and bearing the applicable PMA reference number, must be submitted to the address below.

PMA Post-Approval Study – In accordance with 21 CFR 814.82, the ENDObesity PAS Study is a multicenter, open-label study for the continuing evaluation and periodic reporting of the safety and effectiveness of the TransPyloric Shuttle for weight reduction in obese adults 22 years and older with a BMI of 30-40 kg/m^2. Subjects will be treated with the TransPyloric Shuttle/TransPyloric Shuttle Delivery Device in conjunction with a behavioral modification program. During the treatment phase, subjects will be followed for 12 months or until device removal, whichever occurs earlier. During the weight-loss maintenance phase, all subjects who lost at least 5% Total Body Weight Loss (TBWL) prior to device removal will be followed for an additional 6 months.

Patients who meet the inclusion/exclusion criteria and sign the informed consent to participate in the study will be enrolled. A minimum of 260 patients will be enrolled at up to 15 U.S. sites. Evaluation of at least 200 subjects is required at 12 months post-treatment. A sample size of 260 implanted subjects will provide 99% power to test the hypothesis that the rate of device- and/or procedure-related serious adverse events (SAEs) is less than 6% at 12 months with a test margin of 4%. The minimum acceptable number of evaluable subjects through the weight-loss maintenance phase is 100.

A secondary study objective is to demonstrate that the mean percent Total Body Weight Loss (%TBWL) is greater than 7% at 12 months.

Other study endpoints include the following: proportion of subjects who achieve at least 5% and 10% TBWL, weight loss measured by percent excess weight loss (%EWL), change of BMI from baseline, proportion of subjects who achieve at least one obesity class reduction, change in obesity-related comorbid conditions, device- and/or procedure-related adverse events, incidence of gastric ulcers, early device explants, and weight-loss maintenance at 3- and 6-months post device removal.

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

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.

Be advised that protocol information, interim and final results will be published on the Post Approval Study Webpage http://www.fda.gov/devicepostapproval.

In addition, the results from any 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" (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070974.htm).

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 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, http://www.fda.gov/udi.

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. For more information, please refer to the FDA guidance document entitled, "Modifications to Devices Subject to Premarket Approval (PMA) - The PMA Supplement Decision-Making Process" http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089274.htm.

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 postmarketing safety reporting (21 CFR 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm and on combination product postmarketing safety reporting is available at (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm).

In accordance with the recall requirements specified in 21 CFR 806.10 for devices or the postmarketing safety reporting requirements (21 CFR 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 http://www.fda.gov/Safety/Recalls/IndustryGuidance/default.htm.

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 on the FDA CDRH Internet HomePage located at http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/default.htm. 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, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

If you have any questions concerning this approval order, please contact April Marrone, Ph.D., MBA at (240) 402-6510 or April.Marrone@fda.hhs.gov.

Sincerely,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health