May 14, 2019

BAROnova, Inc.
Lian Cunningham
Senior Vice President, Clinical Affairs & Regulatory Affairs
1551 Industrial Road
San Carlos, California 94070

Re: K190985
Trade/Device Name: BAROnova Insufflation System, BAROnova Accessory Kit
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: FCX, FEQ
Dated: April 12, 2019
Received: April 15, 2019

Dear Lian Cunningham:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. However, you are responsible to determine that the medical devices you use as components in the BAROnova Accessory Kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of

Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Daniel G. Walter, Jr.
Assistant Division Director
DHT3A: Division of Renal, Gastrointestinal, Obesity and Transplant Devices
OHT3: Office of Gastrorenal, ObGyn, General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

Device Name
BAROnova Insufflation System

Indications for Use *(Describe)*
The BAROnova Insufflation System is designed to use air as a distention media in the gastrointestinal tract when used in conjunction with the BAROnova TPS Delivery Device.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

Device Name
BAROnova Accessory Kit

Indications for Use *(Describe)*
The BAROnova Accessory Kit, consisting of the BAROnova Insufflation System, TPS Stand, and Hook Tool is designed to facilitate use of the BAROnova TPS Delivery Device.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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SECTION 5.1: 510(k) SUMMARY STATEMENT

This 510(k) summary is being submitted in accordance with the requirements of the Safe Medical Devices Act of 1990, 21 CFR 807.92.

1. **General Information**

Date of Submission: April 12, 2019

Submitted By: BAROnova, Inc.
1551 Industrial Road
San Carlos, CA 94070

Contact Person: Lian Cunningham, MD, PhD
SVP, Regulatory and Clinical Affairs
Phone 650-638-9796 ext. 22
Fax: 650-638-9094
lcunningham@baronova.com

2. **Device Information:**

Common/Usual Name:	Endoscopic Insufflation System, Accessories
Trade Name:	BAROnova Accessory Kit BAROnova Insufflation System
Regulation Number	876.1500
Regulation Description:	Endoscope and accessories
Product Code:	FCX, FEQ
Device Panel:	Gastroenterology/Urology
Device Classification:	Class II

3. **Legally Marketed Predicate Device for Claimed Equivalence:**

Predicate Device:
Name: Bracco Diagnostics, Inc. CO_2mpact Endoscopic Insufflator™
510(k) #: K111648

Reference Predicate Device:
Name: PARI Trek™ S nebulizer compressor
510(k) #: K060357

4. **Device Description**

The BAROnova Accessory Kit includes the following products:

- BAROnova Insufflation System
- BAROnova Transpyloric Shuttle (TPS) Stand
- Hook Tool

The BAROnova Insufflation System is designed to provide pressure-controlled air to the stomach for insufflation within the gastric space during endoscopic procedures for placement of the BAROnova Transpyloric Shuttle (TPS) device. The Insufflation System is used in conjunction with the BAROnova TPS Delivery Device to facilitate TPS skin expansion during deployment once the Delivery Device is inserted. Prior to initiating TPS coil advancement with the handle controls, the TPS Delivery Device is connected to the reusable Insufflation System using the disposable tubing set provided within the TPS Delivery Device Kit. The reusable components of the Insufflation System are composed of a portable air Compressor, a Power Adapter, and Pressure Regulator Box. The air Compressor and Power Adapter are the identical components as utilized in the PARI Trek S nebulizer (K060357). The Pressure Regulator Box includes a precision low-pressure regulator and redundant pressure relief valves to limit system output pressure. The Box also includes a calibrated pressure gauge for testing and monitoring the performance of the system. The BAROnova Insufflation System allows the physician to deliver pressure-controlled air to the patient in a manner consistent with that being done currently in a routine endoscopic procedure with room air which is supplied by an air pump in the console of the endoscopic equipment.

The TPS Stand (Class I, regulated under 878.4800 – Manual surgical instrument for general use) and Hook Tool (Class I, regulated under 876.4730 – Manual Gastroenterology-Urology Surgical Instrument and Accessories), are optional accessories included in the Accessory Kit for use with the BAROnova TPS Delivery Device. The TPS Stand is a non-sterile, reusable plastic stand with a weighted aluminum base provided for the convenience of the operator, and can be used to support the TPS Delivery Device handle during TPS deployment. The Hook Tool is a stainless steel reusable tool which may be used to facilitate cutting of tension lines for deployment troubleshooting.

5. Indications for Use Statement

Indications for Use for the Accessory Kit:
The BAROnova Accessory Kit, consisting of the BAROnova Insufflation System, TPS Stand, and Hook Tool, is designed to facilitate use of the BAROnova TPS Delivery Device.

Indications for Use for the Insufflation System included within the Accessory Kit:
The BAROnova Insufflation System is designed to use air as a distention media in the gastrointestinal tract when used in conjunction with the BAROnova TPS Delivery Device.

6. Substantial Equivalence Comparison

Indications for Use:
The BAROnova Insufflation System has an almost identical Indication for Use statement as the predicate device listed in this submission. Both the subject device and the predicate device utilize a gas as a distention media in the

gastrointestinal tract. The BAROnova Insufflation System has a narrower indication in that it is designed to be used only with the BAROnova TPS Delivery Device. The Indication for Use statement for the BAROnova Insufflation System meets the standard of substantial equivalence.

Technological Characteristics:
The BAROnova Insufflation System is similar in size and construction to the predicate device, with minor technological differences. The BAROnova Insufflation System operates in a lower overall pressure range than the predicate device providing additional safety against over pressurization within the gastrointestinal system. The BAROnova Insufflation System utilizes air as distension media, while the predicate device uses CO2; however, both air and CO2 are commonly used for GI insufflation so this difference does not affect the substantial equivalence of the devices.

The BAROnova Insufflation System has a similar (narrower) intended use and similar technological characteristics as the listed predicate device and therefore meets the standard of substantial equivalence.

7. Summary of Performance Data (Non-clinical testing)

Non-clinical testing of the subject device for functional and simulated use has been performed, as well as testing to applicable standards. The subject device was found to meet all requirements. The results of the testing performed demonstrate that the BAROnova Insufflation System is safe and effective when used in accordance with its intended use and labeling.

8. Conclusion

Substantial equivalence of the BAROnova Insufflation System (and BAROnova Accessory Kit which contains the Insufflation System, TPS Stand and Hook Tool) is supported by a comparison of the intended use, indications for use, design and materials with the Bracco Diagnostics, Inc. CO_2mpact Endoscopic Insufflator (K111648) as well as acceptable results from verification and validation tests.