July 23, 2019

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

Re: K191078
Trade/Device Name: BAROnova Access Sheath Kit
Regulation Number: 21 CFR 21 CFR 876.1510
Regulation Name: Anchored Esophageal Sheath
Regulatory Class: Class II
Product Code: QGG, FED, OCX, FMF
Dated: April 22, 2019
Received: April 23, 2019

Dear Lian Cunningham:

This letter corrects our substantially equivalent letter of July 22, 2019.

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 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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for
Martha W. Betz, Ph.D.
Acting 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)*
K191078

Device Name
BAROnova Access Sheath Kit

Indications for Use *(Describe)*
The BAROnova Access Sheath Kit is used in conjunction with an endoscope for procedures requiring multiple insertions of the endoscope into the upper gastrointestinal tract, with or without instruments through the instrument channel of the endoscope.
The BAROnova Access Sheath Kit is used in conjunction with the TransPyloric Shuttle Delivery Device to facilitate insertion and positioning of the device during TPS delivery and deployment.
The Access Sheath Kit is NOT indicated for foreign body removal or instrument use alongside the endoscope.

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.

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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 22, 2019

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

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

2. **Device Information:**

Common/Usual Name:	Anchored Esophageal Sheath
Trade Name:	BAROnova Access Sheath Kit
Regulation Number	876.1510
Regulation Description:	Anchored Esophageal Sheath
Product Code:	QGG, FED, OCX, FMF
Device Panel:	Gastroenterology/Urology
Device Classification:	Class II

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

Primary Predicate:

Name:	BAROnova Access Sheath
Accessory Classification #:	Q181451

Secondary Predicates:

Name:	Seal Cap
510(k) #:	K172575
Name:	Hypodermic Syringe
510(k) #:	K980987

4. **Device Description**

The BAROnova Access Sheath Kit includes the following products:

- BAROnova Access Sheath (with obturator)
- Endoscope (Seal) Cap
- Insufflation Syringe

The BAROnova Access Sheath consists of a clean, non-sterile mated Obturator/Access Sheath Assembly. The Access Sheath is composed of thin-walled tubing, a handle and a distal cuff and balloon with an atraumatic tip. The Obturator is made of flexible tubing with an atraumatic tip. The Seal Cap consists of a non-sterile, plastic cap for use with standard endoscopes. A 10cc syringe is also provided with the Access Sheath Kit to enable balloon inflation and deflation.

5. Indications for Use Statement

The BAROnova Access Sheath Kit is used in conjunction with an endoscope for procedures requiring multiple insertions of the endoscope into the upper gastrointestinal tract, with or without instruments through the instrument channel of the endoscope.

The BAROnova Access Sheath Kit is used in conjunction with the TransPyloric Shuttle Delivery Device to facilitate insertion and positioning of the device during TPS delivery and deployment.

The Access Sheath Kit is NOT indicated for foreign body removal or instrument use alongside the endoscope.

6. Substantial Equivalence Comparison

Indications for Use:

The BAROnova Access Sheath Kit has the same indication for use as the predicate BAROnova Access Sheath, thus substantial equivalence is met. No changes have been made to the indication for use for the Endoscope (Seal) Cap and Syringe included within the Access Sheath Kit for convenience. Technological Characteristics:

No changes from the predicate devices have been made to the design, materials, or construction of the BAROnova Access Sheath, Endoscope (Seal) Cap and Syringe included with the BAROnova Access Sheath Kit. The Access Sheath, Endoscope (Seal) Cap and Syringe are packaged together as a convenience kit.

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

Non-clinical testing of the subject devices for structural and functional use has been performed, including dimensional, mechanical, balloon integrity, shaft wall integrity, seal cap functionality, simulated use, animal and biocompatibility. The subject devices were found to meet all requirements.

The results of the testing performed demonstrate that the BAROnova Access Sheath Kit is safe and effective when used in accordance with its intended use and labeling.

8. Conclusion

Substantial equivalence of the BAROnova Access Sheath Kit is supported by a comparison of the intended use, indications for use, design and materials with the predicate devices as well as acceptable results from verification and validation tests.