April 16, 2019

BAROnova, Inc.
Lian Cunningham, MD, Ph.D.
Vice President, Clinical Affairs
1509 Industrial Road
San Carlos, CA 94070

Re: Q181451
BAROnova Access Sheath
Evaluation of Accessory Classification Under Section 513(f)(6) – Accessory Classification Request
Regulation Number: 21 CFR 876.1510
Regulation Name: Anchored Esophageal Sheath
Regulatory Classification: Class II
Product Code: QGG
Dated: July 6, 2018
Received: July 9, 2018

Dear Lian Cunningham:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your Accessory Classification request for classification of the BAROnova Access Sheath, a prescription device under 21 CFR 801.109 that is intended to facilitate insertion and positioning of an endoscope or other compatible device into the upper gastrointestinal tract.

FDA concludes that this device should be classified into class II. This order, therefore, classifies the BAROnova Access Sheath, and substantially equivalent devices of this generic type, into class II under the generic name anchored esophageal sheath.

FDA identifies this generic type of device as:

> **Anchored esophageal sheath.** *Identification.* An anchored esophageal sheath is a device used to provide an endoluminal pathway to facilitate insertion of an endoscope or other compatible device into the upper gastrointestinal tract. A distal anchor assists in keeping the sheath in place to facilitate positioning of the endoscope or other compatible device.

Section 513(f)(6) of the Federal Food, Drug and Cosmetic Act (the FD&C Act) was added by section 707 of the FDA Reauthorization Act of 2017 (FDARA) on August 18, 2017, and was effective on October 17, 2017 (Pub. L. 115-52). This provision establishes a pathway for manufacturers or importers to request classification of accessories distinct from another device upon written request. The classification is based upon the risks of the accessory when used as intended as well as the level of regulatory controls necessary to provide a reasonable assurance of safety and effectiveness, notwithstanding the classification of any other device with which such accessory is intended to be used. Until an accessory is reclassified by FDA, the classification of any accessory distinct from another device by regulation or written order issued prior to December 13, 2016 will continue to apply.

Under section 513(f)(6)(D)(ii) of the FD&C Act, a manufacturer or importer may request proper classification of an accessory that has been granted marketing authorization as part of a premarket approval application (PMA), premarket notification (510(k)), or De Novo classification request. FDA must grant or deny the request not later than 85 days after receipt and, if granting, publish a notice in the **Federal Register** within 30 days announcing the classification.

Alternatively, under section 513(f)(6)(C), a person filing a PMA or 510(k) may include a written request for the proper classification of an accessory that has not been classified distinctly from another device based on the risks of the accessory when used as intended and the level of regulatory controls necessary to provide a reasonable assurance of safety and effectiveness. When the written request is included in a submission for marketing authorization, FDA must grant or deny the request along with the response to the PMA or 510(k). Upon granting, FDA will publish a notice in the **Federal Register** within 30 days announcing the classification.

FDA received your Accessory Classification request on July 9, 2018 to classify the BAROnova Access Sheath into class II under section 513(f)(6)(C) of the FD&C Act. In order to classify the BAROnova Access Sheath into class I or II, the proposed class must have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

After review of the information submitted in the Accessory Classification request and the premarket approval application P180024, FDA has determined that the BAROnova Access Sheath intended to provide an endoluminal pathway to facilitate insertion and positioning of an endoscope or other compatible device into the upper gastrointestinal tract can be classified in class II with the establishment of special controls. FDA has determined that class II (special controls) provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in Table 1.

Table 1 – Identified Risks to Health and Mitigation Measures

Identified Risk(s)	**Mitigation Measure(s)**
Adverse tissue reaction	Biocompatibility evaluation
Mechanical injury to esophagus and/or gastroesophageal junction (GEJ) related to: • Insertion/removal of anchored esophageal sheath • Insertion/removal of endoscope or other compatible device through anchored esophageal sheath • Actuation of anchoring component into anchored configuration within esophagus • Retraction of anchoring component against GEJ	Non-clinical performance testing Simulated use testing Shelf-life testing Labeling

In combination with the general controls of the FD&C Act, the anchored esophageal sheath is subject to the following special controls:

(1) The patient-contacting components of the device must be demonstrated to be biocompatible.

(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be demonstrated:

(i) Dimensional verification;

(ii) Testing must demonstrate that insertion and removal of any device from the anchored esophageal sheath does not damage the shaft wall or exert force that would causes tissue injury;

(iii) Testing must demonstrate that the anchoring component can be reliably actuated;

(iv) Testing must demonstrate compatibility with any other device that the anchored esophageal sheath is intended to be used with; and

(v) Testing must demonstrate device integrity and functionality in simulated gastric conditions under clinically-anticipated forces.

(3) Simulated use testing using an anatomically-accurate gastrointestinal model must demonstrate that:

(i) The device can be inserted and removed safely;

(ii) The device remains anchored in place;

(iii) The device can be safely withdrawn after releasing the anchor; and

(iv) The device location and anchoring status can be observed by the intended user.

(4) Performance data must demonstrate continued device functionality over the identified shelf life.

(5) Labeling must include:

(i) Whether the device can be used for foreign body removal or with instruments alongside the endoscope;

(ii) Steps needed to prevent injury to the esophagus or gastroesophageal junction (GEJ) during placement, anchoring, and use of the device;

(iii) Any visualization steps required to confirm the device's placement prior to and after actuating the anchoring component at the GEJ;

(iv) A precaution to avoid excessive force during insertion;

(v) Identification of any endoscopes or other devices that have been validated for use with the anchored esophageal sheath; and

(vi) An expiration date or shelf life.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Please be advised that FDA's decision to grant this Accessory Classification request does not mean that FDA has determined that your device complies with other requirements of the FD&C Act or any Federal statutes or regulations administered by other Federal agencies. You must comply with all applicable requirements under the FD&C Act, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and, if applicable, 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD&C Act; 21 CFR 1000-1050).

A notice announcing this classification order will be published in the **Federal Register**. A copy of this order is on file in the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may market your device as described in the Accessory Classification request, provided that your device complies with the general control provisions of the FD&C Act and the special controls identified in this order.

If you have any questions concerning this classification order, please contact Allen Chen, Ph.D. at (240)-402-2862.

Sincerely,

/s/

Angela C. Krueger
Deputy Director
for Engineering and Science Review
Office of Device Evaluation
Center for Devices and Radiological Health