July 21, 2022

Bpendo, LLC
% James Fentress
Director, R&D and Regulatory Policy
Gilero, LLC
635 Davis Drive STE 100
Morrisville, NC 27560

Re: K213773
Trade/Device Name: Insufflation Retention Device
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: FDF
Dated: June 14, 2022
Received: June 21, 2022

Dear James Fentress:

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. 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,

Shanil P. Haugen, Ph.D.
Assistant 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213773

Device Name
Insufflation Retention Device

Indications for Use *(Describe)*
The Insufflation Retention Device (IRD) is an accessory to an endoscope. The IRD is a single balloon accessory intended for use with any standard endoscope that has a distal tip outer diameter of 9.2-13.2 mm. The device is indicated to assist with optical visualization in the large intestine during endoscopic procedures.

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.

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510(k) Summary

Company Name: BPENDO, LLC
Company Address: 216 Foreman Circle
Norman, OK 73069
Company Phone: +1 (405) 974-0776

Official Contact: Jim Fentress
Phone: +1 (919) 595-8236
E-mail: jfentress@gilero.com

Submission Date: November 18, 2021

Device Identification:

Trade Name:	Insufflation Retention Device (IRD)
Common Name:	Colonoscope Accessory
Device Class:	2
Regulation Number:	876.1500
Regulation Name:	Endoscope and Accessories
Product Code:	FDF
Review Panel:	Gastroenterology/Urology

Predicate Device:

Manufacturer:	LUMENDI, LLC
Trade Name:	DiLumen Endolumenal Interventional Platform
510(k):	K162428

Device Description:
The IRD is a non-sterile accessory for a colonoscope which provides an adjustable seal between a colonoscope and a patient's anus. This seal retains introduced insufflation air introduced during a colonoscopy. The retained insufflation air provides increased visibility and facilitates the advancement of the colonoscope. The IRD contains a split section which allows it to be placed over the continuous shaft of the colonoscope. The adjustable seal is inflated and deflated manually with a non-sterile syringe.

Indications for Use:
The Insufflation Retention Device (IRD) is an accessory to an endoscope. The IRD is a single balloon accessory intended for use with any standard endoscope that has a distal tip outer diameter of 9.2-13.2 mm. The device is indicated to assist with optical visualization in the large intestine during endoscopic procedures.

Technological Characteristics and Substantial Equivalence:
The following chart presents an overview of comparisons between the subject device (IRD) and the predicate device (DiLumen Endolumenal Interventional Platform):

Device Attribute	SUBJECT: [BPENDO] Insufflation Retention Device	PREDICATE: [Lumendi] DiLumen Endolumenal Interventional Platform
Device Class	2	2
Device Classification Name	Colonoscope and Accessories, Flexible/rigid	Colonoscope and Accessories, Flexible/rigid
Regulation Number	876.1500	876.1500
Product Code	FDF	FDF
Indications for Use and Intended Use	The Insufflation Retention Device (IRD) is an accessory to an endoscope. The IRD is a single balloon accessory intended for use with any standard endoscope that has a distal tip outer diameter of 9.2-13.2 mm. The device is indicated to assist with optical visualization in the large intestine during endoscopic procedures.	The Lumendi DiLumen is an accessory to an endoscope. The DiLumen dual balloon accessory is intended for use with any standard endoscope that has a distal tip outer diameter of 12.5-14.3 mm and a working length of 1680mm or greater. The device is indicated to ensure complete positioning of an endoscope in the large intestine, and assist with optical visualization, diagnosis, and endoscopic treatment
Intended Users	Licensed healthcare practitioners (physicians, nurses, and healthcare professionals (HCPs)	Licensed healthcare practitioners
Intended Use Environment	Professional healthcare facilities	Professional healthcare facilities (Presumed)
Technology and Design	The IRD is constructed from polymeric materials and is designed to access the large intestine through the anus as a colonoscope accessory placed over the colonoscope. The IRD contains a urethane balloon which can be manually inflated and deflated by the user. This balloon, as part of the overall device is inserted into the large intestine through the anus in a deflated state When temporarily inflated by the user, the balloon allows increased visibility of the large intestine through the retention of insufflation gas introduced normally as part of the colonoscopy procedure. The IRD allows free movement of the colonoscope, without compromising the colonoscope function	The DiLumen device is constructed from polymeric materials and is designed to access the large intestine through the anus as a colonoscope accessory placed over the colonoscope. The DiLumen devices contains two urethane balloons which can be manually inflated and deflated by the user. These balloons, as part of the overall device is inserted into the large intestine through the anus in deflated states. When temporarily inflated by the user, the balloons allow increased visibility of the balloon-bounded region of the large intestine . The DiLumen device allows free movement of the colonoscope, without compromising the colonoscope function

Device Attribute	SUBJECT: [BPENDO] Insufflation Retention Device	PREDICATE: [Lumendi] DiLumen Endolumenal Interventional Platform
Principles of Operation	The IRD fits over a colonoscope. The device contains one deflated balloon. After the device has been positioned appropriately at the terminal end of the large intestine (anus), the balloon is manually inflated with air using a syringe. Balloon inflation allows introduced insufflation to provide greater visibility in the large intestine.	The DiLumen device fits over a colonoscope. The device contains two deflated balloons. When positioned appropriately within the large intestines, the balloons are inflated with air using an inflation handle with a squeeze bulb to inflate the balloons within the large intestines. Balloon inflation allows greater visibility in the bounded region in the large intestine.
Biocompatibility	Acceptable biological risk established by demonstrating that the device meets ISO 10993. See Section 15 – Biocompatibility.	Acceptable biological risk established by demonstrating that the device meets ISO 10993
Sterilization	Non-sterile	Non-sterile
Prescription	Rx only	Rx only

Substantial Equivalence:
The Insufflation Retention Device is substantially equivalent to the predicate: LUMENDI, LLC DiLumen Endolumenal Interventional Platform. The subject device and the predicate device have similar indications for use and intended use. Both devices are accessories for colonoscopes which utilize manual, clinician inflation of elastomeric (polyurethane) balloons to stabilize the device in the large intestines. Both devices are used to assist the visibility for clinicians using the endoscope. Both devices accomplish this improved visibility without compromising the use of the endoscope. Both devices are single-use and non-sterile.

Comparison of the three primary technological differences between the subject IRD and the predicate DiLumen devices do not introduce new questions about the safety or efficacy of the subject device. First, while the DiLumen device utilizes two independently inflatable balloons to stabilize the endoscope compared to the single balloon used in the subject IRD device, the balloons serve similar function, and require similar evaluation to verify function. Second, the IRD does not require a balloon extension/retraction mechanism included in the DiLumen device. The omission of these features does not introduce new or different risks. Finally, the subject IRD and the predicate DiLumen devices utilized different materials for their construction, but the subject device was appropriately evaluated for biological safety consistent with its patient contact and duration of use.

Discussion of Non-clinical Tests:
The following non-clinical tests were conducted to demonstrate substantial equivalence to the predicate device.

Biocompatibility:
The IRD, like the predicate device, was evaluated for biocompatibility appropriate to the contact characterization (type and duration), in accordance with the requirements of ISO 10993-1 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process, and the FDA Guidance for Industry - Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". Specific testing included:

- Cytotoxicity
- Sensitization
- Irritation or Intracutaneous Reactivity

Performance Testing:
The following performance data were provided in support of this Premarket Notification:

- Device Placement
- Insertion Force
- Pressure Leak
- Scope diameter testing
- Balloon diameter testing
- Scope movement
- Scope articulation
- Device Removal

- Device security
- Device Shelf life
- Multiple use testing
- Package integrity
- Glove usability
- Use time
- Attachment force
- Balloon feedback
- Connector leakage
- Balloon burst

Conclusion

The information in this submission supports the safety and efficacy of the subject device for its intended use and demonstrates substantial equivalence with the predicate device. The IRD's differences in external materials, technology and operation from the predicate device do not raise new questions about safety and effectiveness.