July 2, 2026

BPEndo, LLC
% Ann Metz
Regulatory Affairs Specialist
Gilero, LLC
4319 S. Alston Ave.
Durham, North Carolina 27713

Re: K261587
Trade/Device Name: Insufflation Retention Device (IRD) (11173-325-101)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: FDF
Dated: June 2, 2026
Received: June 2, 2026

Dear Ann Metz:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261587

Please provide the device trade name(s).

Insufflation Retention Device (IRD) (11173-325-101)

Please provide your Indications for Use below.

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.

Please select the types of uses (select one or both, as applicable).

- [x] Prescription Use (21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

Please select the age group(s) for which the device(s) is to be used.

- [ ] Neonates/Newborns (Birth to < 29 days old)
- [ ] Infants (29 days old to < 2 years old)
- [ ] Children (2 years old to < 12 years old)
- [ ] Adolescents (12 years old to < 22 years old)
- [x] Adults (22 years old and greater)

510(k) Summary

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

Official Contact: Ann Metz
Phone: +1 (262) 955-9774
E-mail: ametz@gilero.com

Submission Date: May 13, 2026

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:	BPEndo, LLC
Trade Name:	Insufflation Retention Device (IRD)
510(k):	K213773

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 BPEndo Insufflation Retention Device (IRD)):

Device Attribute	SUBJECT: K261587 [BPENDO] Insufflation Retention Device	PREDICATE: [BPENDO] Insufflation Retention Device, K213773
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 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.
Intended Users	Licensed healthcare practitioners (physicians, nurses, and healthcare professionals (HCPs)	Licensed healthcare practitioners (physicians, nurses, and healthcare professionals (HCPs)
Intended Use Environment	Professional healthcare facilities	Professional healthcare facilities
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 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
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 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.

Device Attribute	SUBJECT: K261587 [BPENDO] Insufflation Retention Device	PREDICATE: [BPENDO] Insufflation Retention Device, K213773
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: BPEndo Insufflation Retention Device (IRD). 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 primary technological difference between the subject IRD and the predicate IRD devices do not introduce new questions about the safety or efficacy of the subject device. The subject IRD has a resin change to the inflation balloon.

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 the original 510K, K213773. The test methods used in support of this Premarket Notification are the same as in K213773.

• 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 difference in balloon material from the predicate device do not raise new questions about safety and effectiveness.