May 1, 2026

Aspero Medical, Inc.
% Nancy Sauer
Owner and President
Nancy Sauer Regulatory Consulting, LLC
401 Spruce St.
Louisville, Colorado 80027

Re: K260314
Trade/Device Name: Ancora-SB
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: FDA, FED
Dated: January 30, 2026
Received: January 30, 2026

Dear Nancy Sauer:

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260314

Device Name
Ancora-SB

Indications for Use *(Describe)*
The Ancora-SB is an accessory to an endoscope. The Ancora-SB is intended for use with any standard endoscope that has an outer diameter of 9.0 – 9.4 mm and a working length of 1680 mm or greater. The Ancora-SB is intended for use with any standard flexible endoscopy balloon inflation unit with a set pressure of 5.4 kPa (+2.6 kPa, -1.8 kPa). The device is indicated to ensure complete positioning of an endoscope in the small intestine by either oral or anal insertion, and assist with optical visualization, diagnosis, and endoscopic treatment.

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

Date Prepared: April 21, 2026
Prepared by: Nancy Sauer

Manufacturer and 510(k) Owner

Aspero Medical, Inc.
10835 Dover Street, Suite 800, Denver, CO 80021
Phone: (303) 834-7885
Official Contact: Dr. Mark Rentschler, CEO

Submission Correspondent/Consultant

Nancy Sauer, MA
Nancy Sauer Regulatory Consulting llc
Louisville, CO 80027
E-mail: Nancy.sauer4@gmail.com

Device Information

Trade Name:	Ancora-SB
Common Name:	Balloon overtube
Regulation Number:	21CFR 876.1500
Class:	II
Product Codes:	FDA, FED
Review Panel:	Gastroenterology/Urology

Predicate Device Information

Trade Name:	Ancora-SB
Common Name:	Balloon overtube
Regulation Number:	21CFR 876.1500
Class:	II
Product Codes:	FDA, FED
Review Panel:	Gastroenterology/Urology
510(k) Number:	K231323

Device Description

The Ancora-SB is a single-use, close-fitting sleeve that slides freely over a currently marketed standard endoscope having an outer diameter of 9.0 – 9.4 mm and a working length of 1680 mm or greater. The Ancora-SB balloon overtube assembly is a dual lumen silicone tubing that is coaxially coupled to the endoscope by inserting the distal end of the endoscope into the open funnel lumen of the

overtube's proximal handle end assembly and by positioning the overtube as needed. The major lumen has a polyethylene glycol-based hydrophilic lubricious coating to facilitate endoscope insertion and advancement.

The minor lumen provides the air channel for balloon inflation. The Ancora-SB balloon overtube assembly is connected via an air supply tube to a compatible balloon inflation unit. An air supply tube adapter (luer connector) is provided in the package as an optional accessory to facilitate connection with inflation units where such an adapter is needed.

When the textured balloon near the distal end is inflated by the balloon inflation unit, it can either stabilize the position of endoscope in the intestine or it can facilitate advancement of the endoscope through a maneuver know as plication.

Indications for Use

The Ancora-SB is an accessory to an endoscope. The Ancora-SB is intended for use with any standard endoscope that has an outer diameter of 9.0 – 9.4 mm and a working length of 1680 mm or greater. The Ancora-SB is intended for use with any standard flexible endoscopy balloon inflation unit with a set pressure of 5.4 kPa (+2.6 kPa, -1.8 kPa). The device is indicated to ensure complete positioning of an endoscope in the small intestine by either oral or anal insertion, and assist with optical visualization, diagnosis, and endoscopic treatment.

Comparison of Modified Ancora-SB to Predicate Device

Aspero Medical, Inc. submitted this traditional 510(k) because to gain clearance for changes in materials and specification changes that met the criteria for a new 510(k) when analyzed according to the criteria in the 2017 FDA guidance document "Deciding When to Submit a 510(k) for a Change to an Existing Device."

There are no changes to the indications for use or the intended use of the Ancora-SB.

The table below compares the technological characteristics of the modified Ancora-SB to those of the originally cleared Ancora-SB.

Characteristic	Modified Ancora-SB	Original Ancora-SB
Target Areas of Use	Small intestine	Small intestine
Device Introduction Site	Oral or anal	Oral or anal
Device components	Single use splinting tube Air supply assembly Luer adapter	Single use splinting tube Air supply assembly Luer adapter

Characteristic	Modified Ancora-SB	Original Ancora-SB
Operating Principle and Design	Dual lumen silicone tubing with major lumen having hydrophilic lubricious coating to facilitate endoscope insertion and minor lumen as air channel for balloon inflation. Proximal end is a funnel handle with endoscope access, air tubing attachment, and irrigation syringe attachment to activate lubricious coating. Distal end features a soft rounded end cap, a radiopaque marker, and a silicone balloon with a textured surface that contacts the mucosa during use.	Dual lumen silicone tubing with major lumen having hydrophilic lubricious coating to facilitate endoscope insertion and minor lumen as air channel for balloon inflation. Proximal end is a funnel handle with endoscope access, air tubing attachment, and irrigation syringe attachment to activate lubricious coating. Distal end features a soft rounded end cap, a radiopaque marker, and a silicone balloon with a textured surface that contacts the mucosa during use.
Balloon Outer Diameter	38 mm	38 mm
Balloon Injection Volume	43 mL	43 mL
Insertion Tube Maximum Insertion Width	15.9 mm	15.9 mm
Insertion Tube Inner Diameter	11 mm	11 mm
Insertion Tube Working Length	132 cm	132 cm
Insertion Tube Total Length	140 cm	140 cm
Air Flow Tube Length	370 cm	370 cm
Materials	Funnel handle: Silicone with titanium dioxide, external laser marking Tube: Silicone with PEG-based hydrophilic coating of the lumen interior Balloon: Silicone Radiopaque feature on distal end: Barium sulfate (25%) impregnated silicone	Funnel handle: Silicone, external printing – polyurethane-based ink Tube: Silicone with PVP-based hydrophilic coating of the lumen interior Balloon: Silicone Radiopaque feature on distal end: platinum
Balloon	Single textured balloon on distal end of splinting tube	Single textured balloon on distal end of splinting tube
Balloon Inflation Method	Standard flexible endoscopy balloon inflation unit with a set pressure of 5.4 (+2.6/-1.8) kPa.	Standard flexible endoscopy balloon inflation unit with a set pressure of 5.4 (+2.6/-1.8) kPa.
Proximal End Connections	Endoscope insertion port Fluid/flush port Air/inflation port	Endoscope insertion port Fluid/flush port Air/inflation port
Sterility	Non-sterile	Non-sterile

Characteristic	Modified Ancora-SB	Original Ancora-SB
Shelf Life	12 months	12 months

The primary differences are in the formulation of the hydrophilic coating of the overtube lumen and a revised proprietary test method. These interrelated changes are intended to ensure acceptable levels of friction even in challenging use cases.

This 510(k) also reports a change in the radiopaque feature at the distal end of the overtube.

Summary of Non-Clinical Testing

Biocompatibility was evaluated in accordance with ISO 10993-1: 2018 and the associated FDA guidance document. This evaluation demonstrated acceptable biocompatibility for the device's intended use.

Bench testing was limited to evaluation of characteristics affected by the material and/or specification changes.

- The new hydrophilic coating demonstrated acceptably low friction under test conditions simulating challenging use cases.
- The modified end cap continued to meet specifications for a secure bond between the cap and the rest of the overtube.
- The modified end cap was found to have acceptable radiopacity.

Conclusion

The modified Ancora-SB is substantially equivalent to the originally cleared Ancora-SB. This conclusion is based on the following information:

- The indications for use and the operating principle are the same.
- There are a limited number of technological changes that do not raise new issues of safety or effectiveness when compared to the predicate device.
- Appropriate methods exist to evaluate the technological changes, and the results of testing support a conclusion of substantial equivalence.