August 31, 2023

Aspero Medical, Inc.
% Pierre Bounaud
Principal Consultant
Rqm+
2251 San Diego Ave, Suite B-257
San Diego, California 92110

Re: K231323
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: July 31, 2023
Received: July 31, 2023

Dear Pierre Bounaud:

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 -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
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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.

Submission Number *(if known)*

K231323

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.

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510(k) Summary

DATE PREPARED
July 31, 2023

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DEVICE INFORMATION

Proprietary Name/Trade Name:	Ancora-SB
Regulation Name:	Endoscope and accessories
Regulation Number:	21 CFR 876.1500
Class:	II
Product Codes:	FDA, FED
Premarket Review:	OPEQ/OHT3/Renal, Gastrointestinal, Obesity and Transplant Devices (DHT3A)
Review Panel:	Gastroenterology/Urology

PREDICATE DEVICE IDENTIFICATION
The Ancora-SB is substantially equivalent to the following predicates:

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*	*Reference Device*
K071254	Splinting Tube ST-SB1 (accessory to Small Intestinal Videoscope System) / Olympus Medical Systems Corp.	✓	
K221452	DiLumen C1, EZ1 and Tool Mount / Lumendi, LLC		✓

The predicate devices have not been subject to a design related recall.

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 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. The device is designed to be used with a Balloon Endoscopy System (BES) which includes a multi-channel endoscope, an endoscopy tower (light source, display monitor, recording equipment, etc.) and a balloon inflation unit (equipment that inflates or deflates by a push button control, inflation is to a stated maximum pressure and the pressure is maintained during active use when inflated).

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 TECHNOLOGICAL CHARACTERISTICS

Aspero Medical, Inc. believes that the Ancora-SB is substantially equivalent to the predicate device based on the information summarized here:

The subject device has the same intended use, i.e., it is a single use tube intended 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, as the splinting tube ST-SB1 cleared as an accessory in K071254.

The subject device has similar technological characteristics (same operating principle, similar design and dimensions, similar materials). as the splinting tube ST-SB1 cleared as an accessory in K071254. Differences in technological characteristics includes the following:

- The silicone balloon of the subject device features a proprietary textured surface designed to provide stability and advancement of the endoscope. Smooth, round balloons currently on the market, such as the one on the splinting tube ST-SB1, are prone to slippage against the mucosa, reducing the time efficiency of small bowel enteroscopy procedures.
- The Ancora-SB is provided non-sterile. This is similar to the reference device cleared in K221452.

These technological characteristics have undergone testing to ensure the device is as safe and effective as the predicates.

Table below provides a summary of the technological characteristics of the subject device compared to the predicate and reference devices.

	Subject Device	*Primary Predicate Device*	*Reference Device*
	Ancora-SB	**Splinting Tube ST-SB1 (Accessory to Small Intestinal Videoscope System)** **K071254**	**DiLumen C1, EZ1 and Tool Mount** **K221452**
Product Codes / Regulation Number	FDA / 21 CFR 876.1500 FED / 21 CFR 876.1500	Same	FDF / 21 CFR 876.1500
Intended Use	Single use tube intended 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.	Same	Single use tube intended to ensure complete positioning of an endoscope in the large intestine, and assist with optical visualization, diagnosis, and endoscopic treatment.
Device Components	• Single Use Splinting Tube • Air supply tube assembly • Luer adaptor	• Small Intestinal Videoscope • Single Use Splinting Tube (ST-SB1) • Balloon Control Unit (OBCU) • Accessories	• Sleeve • Manual inflation bulb
Balloon Outer Diameter	38 mm	40 mm	60 mm
Balloon Injection Volume	43 mL	Same[1]	Unknown
Insertion Tube Maximum Insertion Width	15.9 mm	Same	Unknown
Insertion Tube Inner Diameter	11 mm	Same	Unknown
Insertion Tube Working Length	1,320 mm	Same	1,300 mm
Insertion Tube Total Length	1,400 mm	Same	Unknown
Air Flow Tube Length	3,700 mm	Same	Unknown
Materials	Hydrophilic-coated silicone Radiopaque material on distal	Same	Hydrophilic-coated extruded polyurethane

	Subject Device	*Primary Predicate Device*	*Reference Device*
	Ancora-SB	**Splinting Tube ST-SB1 (Accessory to Small Intestinal Videoscope System)** **K071254**	**DiLumen C1, EZ1 and Tool Mount** **K221452**
	end		Low durometer polyurethane (balloon) Radiopaque material on distal end
Balloon	Single textured balloon on distal end of splinting tube	Single smooth balloon on distal end of splinting tube	Single smooth balloon on distal end of splinting tube
Balloon Inflation Methods	Standard flexible endoscopy balloon inflation unit with a set pressure of 5.4 (+2.6/-1.8) kPa.	Olympus OBCU delivering set inflation pressure of 5.4 (+2.6/-0) kPa	Integrated manual inflation bulb
Proximal End Connections	• Endoscope insertion port • Fluid/flush port • Air/inflation port	Same	Same
Sterilization Method	Non-sterile	EO	Same
Compatible Endoscopes	Any standard endoscope with a distal tip outer diameter of 9.0 – 9.4 mm and a working length of 1680 mm or greater	Olympus SIF Type Q180, Q260, each having outer diameter of 9.2 mm and working length of 2000 mm.	Any standard endoscope with a distal tip outer diameter of 12.5 – 14.3 mm and a working length of 1680 mm or greater

[1]Volume of air needed to reach the outside diameter specification (40 mm) of the balloon in a commercial splinting tube ST-SB1, as measured by Aspero Medical.

SUMMARY OF NON-CLINICAL TESTING

The following tests were performed to demonstrate safety based on current industry standards:

- Biocompatibility testing per ISO 10993-1, -5, -10, and -23
- Distribution testing per ASTM D4169-22
- Shelf-life testing per ASTM F1980-21
- Bench performance testing including dimension inspection, packaging inspection, components and features inspection, balloon compatibility and reliability, overtube friction force and reliability, balloon inflation time, balloon anchor force, and joint strength
- GLP animal study

The results of these tests indicate that the Ancora-SB is substantially equivalent to the predicate device.

CONCLUSION

Based on the testing performed, it can be concluded that the subject device does not raise new issues of safety or effectiveness compared to the predicate device. The similar indications for

use, technological characteristics, and performance characteristics for the proposed Ancora-SB are assessed to be substantially equivalent to the predicate device.