October 10, 2025

EvoEndo, Inc.
% Keira Jessop
Regulatory Affairs Consultant
AlvaMed, Inc.
935 Great Plain Avenue
Unit 166
Needham, Massachusetts 02492

Re: K251708
Trade/Device Name: EvoEndo Single-Use Endoscopy System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: FDS, FET
Dated: September 12, 2025
Received: September 12, 2025

Dear Keira Jessop:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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,

SIVAKAMI VENKATACHALAM -S

for
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)*
K251708

Device Name
EvoEndo Single-Use Endoscopy System

Indications for Use *(Describe)*
The EvoEndo Model LE Gastroscope is intended for the visualization of the upper digestive tract in adults and pediatric patients, specifically for the observation, diagnosis, and endoscopic treatment of the esophagus, stomach, and duodenal bulb. The gastroscope is a sterile single-use device and can be inserted orally or transnasally. The 110 cm gastroscope is intended to be used in adult and pediatric populations. The 85 cm gastroscope is intended to be used in the pediatric population.

The EvoEndo Controller is intended for use with an EvoEndo Endoscope for endoscopic diagnosis, treatment, and video observation.

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

K251708

1.1 Name and Address of Submitter

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1.2 Correspondent/Primary Contact Person

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1.3 Submission Information

Date Summary Prepared: September 29, 2025

Subject Device:	Trade/Device Name:	EvoEndo Single-Use Endoscopy System
	Manufacturer:	EvoEndo, Inc.
	Common Name:	Gastroscope and accessories, flexible/rigid Endoscopic video imaging system/ Component, Gastroenterology-Urology
	Regulation Number:	21 CFR 876.1500
	Regulation Name:	Endoscope and accessories
	Regulation Class	Class II
	Product Code:	FDS, FET
	Review Panel:	Gastroenterology/Urology

Predicate Device:	Clearance:	K213606
	Trade/Device Name:	EvoEndo Single-Use Endoscopy System
	Manufacturer:	EvoEndo, Inc.
	Regulation Number:	21 CFR 876.1500
	Regulation Name:	Endoscope and accessories
	Regulation Class	Class II

Valid Predicate Discussion

EvoEndo Single-Use Endoscopy System was selected as the valid predicate device used to support the 510(k) submission because it was cleared using well-established methods and this submission is to address design changes to the predicate device. After conducting a search on the Manufacturer and User Facility Device Experience (MAUDE) Database, Medical Device Reporting (MDR), MedSun Reports Database, Medical Device Safety and CBER Safety & Availability (Biologics) and Recall Database websites it was confirmed that there are no known unmitigated use-related or design safety issues and the predicate device has not been subject to a design-related recall.

Table 1: Valid Predicate Device

Valid Predicate Device	**A - Well established methods**	**B - Meets or exceeds expected predicate performance**	**C - Unmitigated use-related or design-related safety issues**	**D – Associated design-related recall**
EvoEndo Single-Use Endoscopy System	Used relevant methods that were published in the public domain.	History of Safe use, established due to duration of device on the market	No known unmitigated use-related or design related safety issues	No design-related recall identified

1.4 Device Description

The EvoEndo Endoscopy System is comprised of three regulated components:

- EvoEndo Model LE Single-Use Gastroscope (hereafter referred to as the EvoEndo Endoscope)
- EvoEndo Reusable Video Cable (hereafter referred to as the Video Cable)
- EvoEndo Controller (hereafter referred to as the Controller)

The EvoEndo Endoscope is a sterile, single-use gastroscope intended to perform oral or transnasal diagnostic endoscopy in adult and pediatric patients. The EvoEndo Endoscope is ethylene oxide (EO) sterilized and is comprised of:

- Handle
- Umbilical Bundle that includes air, water, and suction lines, as well as the video connector
- Endoscope shaft with HD Camera

The Controller of the EvoEndo Endoscopy System translates the images or video captured by the camera at the distal end of the EvoEndo Endoscope to a monitor via an HDMI cable.

1.5 Indications for Use

The EvoEndo Model LE Gastroscope is intended for the visualization of the upper digestive tract in adults and pediatric patients, specifically for the observation, diagnosis, and endoscopic treatment of the esophagus, stomach, and duodenal bulb. The gastroscope is a sterile single-use device and can be inserted orally or transnasally. The 110 cm gastroscope is intended to be used in adult and pediatric populations. The 85 cm gastroscope is intended to be used in the pediatric population.

The EvoEndo Controller is intended for use with an EvoEndo Endoscope for endoscopic diagnosis, treatment, and video observation.

1.6 Summary of Technological Characteristics

The following table provides an overview of general technological characteristics in comparison to the predicate device.

Table 2: Comparison of Predicate Device and Subject Device

	Subject Device	Predicate Device
510(k) Number	K251708	K213606
Sponsor	EvoEndo, Inc	EvoEndo, Inc
Device Name	EvoEndo Endoscopy System	EvoEndo Endoscopy System
Product Code	FDS, FET	FDS, FET
Indications for Use	The EvoEndo Model LE Gastroscope is intended for the visualization of the upper digestive tract in adults and pediatric patients, specifically for the observation, diagnosis, and endoscopic treatment of the esophagus, stomach, and duodenal bulb. The gastroscope is a sterile single-use device and can be inserted orally or transnasally. The 110 cm gastroscope is intended to be used in adult and pediatric populations. The 85 cm gastroscope is intended to be used in the pediatric population. The EvoEndo Controller is intended for use with an EvoEndo Endoscope for endoscopic diagnosis, treatment, and video observation.	The EvoEndo Model LE Gastroscope is intended for the visualization of the upper digestive tract in adults and pediatric patients, specifically for the observation, diagnosis, and endoscopic treatment of the esophagus, stomach, and duodenal bulb. The gastroscope is a sterile single- use device and can be inserted orally or transnasally. The EvoEndo Controller is intended for use with an EvoEndo Endoscope for endoscopic diagnosis, treatment, and video observation.
Endoscope Outer Diameter	3.5mm	3.5mm
Working Channel Diameter	2.0mm	2.0mm
Working Length	110cm and 85cm	110cm
Field of View	120°	120°
Steering Method	4-way	4-way
Maximum Bending Angle	Up 210° Down 90° Left 180° Right 180°	Up 210° Down 90° Left 100° Right 100°

	Subject Device	**Predicate Device**
Shaft Design	Multi-lumen braid reinforced Pebax	Multi-lumen extrusion made of Pebax
Air, Water, Suction (AWS) Functionality	Yes	Yes
Video Inputs	Ferric HDMI Cable & USB 3.0 Cable	Ferric HDMI Cable & USB 3.0 Cable
Monitor Compatibility	Medical grade monitor (27-inch, 1080p HD resolution recommended)	Medical grade monitor (27-inch, 1080p HD resolution recommended)
Illumination Technology	Located in EvoEndo Endoscope	Located in EvoEndo Endoscope
Electrical Specifications Input Voltage	100 – 240 VAC, 50-60 Hz 0.5A	100 – 240 VAC, 50-60 Hz 0.5A
U.S. Power Cord Specifications	115 VAC Length – 1.5 meters Voltage Rating – 240 VAC Current Rating – 12 A Connector Type – Horizontal	115 VAC Length – 1.5 meters Voltage Rating – 240 VAC Current Rating – 12 A Connector Type – Horizontal
Packaging	Plastic card with a HDPE Tube over device shaft sealed in a Tyvek pouch	Thermoform tray sealed into a Tyvek pouch
Controller Physical Specifications		
Material	Aluminum	Aluminum
Height	6.0 cm	6.0 cm
Weight	15.0 cm	15.0 cm
Depth	21.5 cm	21.5 cm
Firmware		
Controller Firmware	Options for “Image enhance” (gamma correction), user-programmable function, image freeze, and white-balance reset.	Options for image and video capture and white-balance reset

1.7 Performance Testing Summary

Summary of Biocompatibility Testing

The EvoEndo Model LE Gastroscope is considered to be a surface device with breached or compromised surfaces contact with a limited duration (< 24 hrs). The biocompatibility evaluation for the EvoEndo Model LE Gastroscope was conducted in accordance with the guidance document "Use of International Standard ISO 10993-1, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing Within a Risk Management Process,'" The testing included the following:

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic Toxicity
- Material Medicated Pyrogenicity

Summary of Non-Clinical Functional and Performance Testing

Visual, dimensional, functional, and transit simulation verification testing was performed on final sterilized EvoEndo Endoscopes. In functional testing, devices were verified for camera and video control unit functioning; tip deflection; air, water, and suction flow rates; functionality with accessory device; functionality after 360° bend shaft orientation; functionality with simulated repeated use; and post simulated use functionality. The maximum bending angle of the device in each direction is shown in the table below. The deflection achieved with the EvoEndo Endoscope is considered equal or greater to that of the identified predicate device in all directions, indicating substantial equivalence.

Table 3: Deflection of EvoEndo Endoscope

Deflection Direction	Maximum Bending Angle
Up	210°
Down	90°
Left	180°
Right	180°

In transit simulation testing, test units underwent environmental conditioning, distribution simulation, and packaging testing to confirm the integrity of the sterile barrier and functionality of the device under expected transportation conditions. The EvoEndo Endoscopy System met acceptance criteria set for all verification testing procedures.

Photobiological safety testing was performed per FDA recognized consensus standard IEC/TR 62471 First Edition 2006-07: Photobiological safety of lamps and lamp systems. Based on the measured output of the EvoEndo's light source, it was

deemed to be below the limits of the exempt risk group.

Summary of Usability Engineering Testing:

EvoEndo conducted a usability study of representative intended users. The study assessed the overall usability of the EvoEndo Endoscopy System and the ability for users to perform critical tasks. Participants were asked to perform the entire workflow of the device across a benchtop model with prior training provided. Throughout the procedure, there were no significant device or user malfunctions or errors that would result in patient harm during an actual procedure.

Summary of Animal and Clinical Data

No animal or clinical studies were conducted for this submission.

1.8 Shelf Life and Sterilization

The EvoEndo Endoscope is packaged individually, provided sterile, labeled for single use only, and sterilized using 100% ethylene oxide (EO) gas in a fixed chamber. Validation performed for the sterilization technique met all acceptance criteria. Functional testing confirmed that sterilization did not impact product safety or effectiveness. The predicate device (K213606) was cleared with a shelf life of 6 months. Additional testing done using the same methods as the predicate in K213606 was performed. Based on the testing performed the labeled shelf life will be 12-months.

1.9 Electrical Safety and EMC Testing:

The Electrical Safety (ES) and Electromagnetic Compatibility (EMC) testing conformed to IEC 60601-1 Ed. 3.2 en:2020, IEC 60601-1-2:2014/AMD1:2020, IEC 60601-2-18:2009, and IEC 62471, Ed 1.0 (2006-07). All acceptance criteria were met.

1.10 Software Testing:

The firmware used in the EvoEndo Controller has been determined to be a basic level of concern. The software in the controller, consisting of 6 embedded firmware items, is considered off-the-shelf software and, as such, is documented in accordance with the FDA Guidance “Off- The-Shelf Software Use in Medical Devices” (August 2023).

1.11 Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification that it can be concluded that the subject device is substantially equivalent with predicate device.