October 3, 2025

Olympus Medical Systems Corporation
% Teffany Hutto
Project Manager, Regulatory Affairs
Olympus Corporation of the Americas
800 West Park Drive
Westborough, Massachusetts 01581

Re: K251859
Trade/Device Name: EVIS EUS Ultrasound Gastrointestinal Videoscope (Olympus GF-UE190)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: ODG, ITX
Dated: September 4, 2025
Received: September 4, 2025

Dear Teffany Hutto:

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,

Shanil P. Haugen -S

Shanil P. Haugen, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal, Obesity and Transplant Devices
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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)*
K251859

Device Name
EVIS EUS ULTRASOUND GASTROINTESTINAL VIDEOSCOPE (OLYMPUS GF-UE190)

Indications for Use *(Describe)*
The EVIS EUS ULTRASOUND GASTROINTESTINAL VIDEOSCOPE OLYMPUS GF-UE190 has been designed to be used with diagnostic ultrasound system, video system center, light source, documentation equipment, monitor, endoscopic therapy accessories and other ancillary equipment.

The EVIS EUS ULTRASOUND GASTROINTESTINAL VIDEOSCOPE OLYMPUS GF-UE190 is designed for endoscopic real-time ultrasound imaging, and other endoscopic procedures within the upper gastrointestinal tract and surrounding organs.

Operator qualifications
Appropriately trained healthcare professionals.

Device use settings
Healthcare facility

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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Date Prepared: September 30, 2025

510(k) Summary

1. GENERAL INFORMATION

■ 510(k) Submitter: OLYMPUS MEDICAL SYSTEMS CORP.
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■ Contact Person: Teffany Hutto
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■ Manufacturing site: Aizu Olympus Co., Ltd.,
3-1-1 Niiderakita, Aizuwakamatsu-shi, Fukushima 965-8520, Japan

2. DEVICE IDENTIFICATION

Trade/Device Name	EVIS EUS ULTRASOUND GASTROINTESTINAL VIDEOSCOPE OLYMPUS
Model Name	GF-UE190
Common Name	Gastroscope and accessories, flexible/rigid
Regulation Number	21 CFR 876.1500
Regulation Name	Endoscope and accessories
Regulatory Class	II
Product Code	ODG (Endoscopic ultrasound system, gastroenterology-urology) ITX (Transducer, ultrasonic, diagnostic)
Classification Panel	Radiology

3. PREDICATE DEVICE / REFERENCE DEVICE

Predicate Device Name	510(k) Submitter	510(k) No.
OLYMPUS GF-UE160-AL5 Endoscope used with the Aloka SSD-5000 Diagnostic Ultrasound System	OLYMPUS MEDICAL SYSTEMS CORP.	K051541

Reference Device Name	510(k) Submitter	510(k) No.
Gastrointestinal Videoscope OLYMPUS GIF TYPE HQ190 (GIF-HQ190)	OLYMPUS MEDICAL SYSTEMS CORP.	K112680

4. DEVICE DESCRIPTION

The EVIS EUS ULTRASOUND GASTROINTESTINAL VIDEOSCOPE OLYMPUS GF-UE190 has been designed to be used with diagnostic ultrasound system, video system center, light source, documentation equipment, monitor, endoscopic therapy accessories and other ancillary equipment.

The EVIS EUS ULTRASOUND GASTROINTESTINAL VIDEOSCOPE OLYMPUS GF-UE190 is designed for endoscopic real-time ultrasound imaging, and other endoscopic procedures within the upper gastrointestinal tract and surrounding organs.

5. PRINCIPLE OF OPERATION

The GF-UE190 has been designed to be used with diagnostic ultrasound system, video system center, light source, documentation equipment, monitor and endoscopic therapay accessories and other ancillary equipment. This instrument is designed for endoscopic real-time ultrasound imaging, and other endoscopic procedures within the upper gastrointestinal tract, anus, rectum, and surrounding organs.

The GF-UE190 is a flexible video endoscope and modification of the GF-UE160-AL5 that was previously cleared under K051541. The subject device consists of three parts: the control section, the insertion section, and the connector section.

The Control Section

The RIGHT/LEFT and UP/DOWN angulation control knob on the control section is connected to the tip of the tip of the bending section by a series of wires. By operating the RIGHT/LEFT and UP/DOWN angulation control knob, the bending section at the distal end bends vertically to guide the distal end for insertion and observation within the gastrointestinal tract.

The control section contains two cylinders: the suction cylinder and the air/water cylinder. The suction valve is attached to the suction cylinder and the air/water valve is attached to the air/water cylinder. When suction valve is depressed to the first stage to activate suction, the suction valve is operated to remove any fluids, debris, flatus, or air from the patient. The suction valve is depressed completely to activate suction of the water from the balloon through the balloon channel. The hole in the air/water valve is covered to insufflate air and the air/water valve is depressed to the first stage to feed water for lens washing. It also can be used to feed air to remove any

fluid or debris adhering to the objective lens. The air/water valve is depressed completely to fill the balloon with sterile water through the balloon channel.

The Insertion Section

The insertion section has main parts including the image sensor, light guides that bring light from the light source through the endoscope, instrument channel where therapeutic tools can be pushed in and out (also the suction channel), and the ultrasound transducer that emits and receives ultrasound waves. The light from the light source travels through the light guide to the light guide lens at the distal end. The light source can offer both the white light for the normal observation and the narrow band imaging (NBI). The image sensor transduces the incident light from the objective lens to electrical signal. The video processor transduce electrical signal to video signal.

The Endoscope Connector Section

The connector section has the endoscope connector that connects the endoscope with the light source (CLV-190 or CV-1500). The connector section also has the ultrasound cable connector. This ultrasound cable connector connects the endoscope with the Olympus ultrasound center through the ultrasound cable. The Ultrasound (US) Connector cap attached to the ultrasound cable connector protects the endoscope from water penetration during reprocessing.

The basic principle, including user interface and operation of the GF-UE190, are almost the same to the predicate GF-UE160-AL5.

The subject device has been designed to be used with the following systems:

- EU-ME3: K243502
- Aplio i800: K233195
- EVIS EXERA III 190 System: K112680, K121959
- EVIS X1 1500 System: K222584

6. INDICATIONS FOR USE

The EVIS EUS ULTRASOUND GASTROINTESTINAL VIDEOSCOPE OLYMPUS GF-UE190 has been designed to be used with diagnostic ultrasound system, video system center, light source, documentation equipment, monitor, endoscopic therapy accessories and other ancillary equipment.

The EVIS EUS ULTRASOUND GASTROINTESTINAL VIDEOSCOPE OLYMPUS GF-UE190 is designed for endoscopic real-time ultrasound imaging, and other endoscopic procedures within the upper gastrointestinal tract and surrounding organs.

Operator qualifications
Appropriately trained healthcare professionals.

Device use settings
Healthcare facility

INDICATIONS FOR USE COMPARISON

The indications for use for the subject device, GF-UE190, is similar as the predicate device, GFUE160-AL5. The main difference is that the compatible ultrasound system cleared for use with the predicate device is different than the systems to be used with the subject device. Testing included in this application will show that these new ultrasound systems will not introduce new issues of safety or efficacy.

7. COMPARISON OF TECHNOLOGY CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject and predicate devices have the same design, materials, principle operation, and energy source. The subject and predicate devices do have different technological characteristics which are listed as follows:

1) Outer diameter of distal end
Outer diameter of distal end has been narrowed from Φ13.8 mm to Φ13.4 mm. Compared to the Predicate Device; the outer diameter of the distal end is smaller. However, this difference does not affect the indications for use, device function or performance. Risk Analysis did not identify any new risks related to this difference. Therefore, this difference will not introduce new issues of safety or efficacy.

2) Maximum outer diameter of distal end
Maximum outer diameter of distal end has been narrowed from Φ15.0 mm to Φ14.7 mm. Compared to the Predicate Device; the maximum outer diameter of the distal end is smaller. However, this difference does not affect the indications for use, device function or performance. Risk Analysis did not identify any new risks related to this difference. Therefore, this difference will not introduce new issues of safety or efficacy.

3) Outer diameter of insertion tube
Outer diameter of insertion tube has been narrowed from Φ11.8 mm to Φ10.9 mm. Compared to the Predicate Device; the outer diameter of the insertion tube is smaller. However, this difference does not affect the indications for use, device function or performance. Risk Analysis did not identify any new risks related to this difference. Therefore, this difference will not introduce new issues of safety or efficacy.

4) Direction of view

Direction of view has been changed from 55° to 50°. Compared to the Predicate Device, the direction of view is closer to forward viewing. However, this difference does not affect the indication for use, device function or performance. Risk Analysis did not identify any new risks related to this difference. Therefore, this difference will not introduce new issues of safety or efficacy.

5) Electrical connector (transmit CCD image signal) and ultrasound connector (transmit ultrasound image signal)

Electrical connector and ultrasound connector are integrated with scope connector. Water-resistant cap for the electrical connector is no longer needed. On the other hand, ultrasound cable (MAJ-2056 or UITC-AI800A) is needed to communicate with ultrasound system. This is only mechanical structure change, and no modification is applied to its operation or communication with the video system center and ultrasound system. Therefore, this difference will not introduce new issues of safety or efficacy.

6) Shape of distal end

There is a D-cut at the distal end. This change aims to remove the band of balloon easily if the band of the balloon's distal end is left on the endoscope's balloon attachment groove. Insert a tool into the balloon attachment groove's notch and pull off the band to take it off. Cleaning validation was performed and confirmed that GF-UE190 can be cleaned effectively.

7) Outlet of the balloon suction channel

By changing the outlet shape of the balloon suction channel, the cleaning brush can be confirmed from the outlet of the balloon suction channel. This change aims to easily confirm that the cleaning brush has fully passed the whole length of the balloon suction channel. Cleaning validation was performed and confirmed that GF-UE190 can be cleaned effectively.

8) Structure of transducer cover

By changing the structure of the transducer cover, the edge of the acoustic lens can be covered. This change aims to prevent peeling of the edge of the acoustic lens. Cleaning validation was performed and confirmed that GF-UE190 can be cleaned effectively.

9) Shear Wave Elastography (SWE)

The GF-UE190 is compatible with Aplio i800 (K233195) and OLYMPUS EU-ME3 (K243502) which has Shear Wave Elastography (SWE) technology. SWE is an ultrasound applied technique used to measure tissue stiffness. In SWE, shear wave is transmitted from acoustic lens and the propagation velocity is measured when the wave passes the tissue. The ultrasound transmission in SWE is within the range of the IEC 60601-2-37 and the ultrasound output standard (MI ≤ 1.9, ISPTA.3 ≤ 720 mW/cm2) set by FDA. Therefore, this difference will not introduce new issues of safety or efficacy.

A side-by-side comparison of the subject device and the predicate device is provided below.

Item	Subject Device (SD)	Predicate Device (PD)
General Information		
Model	EVIS EUS ULTRASOUND GASTROINTENSTINAL VIDEOSCOPE OLYMPUS GF-UE190	OLYMPUS GF-UE160-AL5 Endoscope used with the Aloka SSD-5000 Diagnostic Ultrasound System
Company	OLYMPUS MEDICAL SYSTEMS CORP.	OLYMPUS MEDICAL SYSTEMS CORP.
510(k) Number	-	K051541
Indications for use	The EVIS EUS ULTRASOUND GASTROINTESTINAL VIDEOSCOPE OLYMPUS GF-UE190 has been designed to be used with diagnostic ultrasound system, video system center, light source, documentation equipment, monitor, endoscopic therapy accessories and other ancillary equipment. The EVIS EUS ULTRASOUND GASTROINTESTINAL VIDEOSCOPE OLYMPUS GF-UE190 is designed for endoscopic real-time ultrasound imaging, and other endoscopic procedures within the upper gastrointestinal tract and surrounding organs. <u>Operator qualifications</u> Appropriately trained healthcare professionals. <u>Device use settings</u> Healthcare facility	The Olympus GF-UE160-AL5 Ultrasonic Endoscope is intended to be used for endoscopic ultrasonic imaging of the gastrointestinal wall, bile and pancreatic ducts and surrounding organs. It is to be used with the Aloka SSD-5000 (K033311) Diagnostic Ultrasound system and various other video and light source accessories.
Regulation name	Endoscope and accessories	Endoscope and accessories, Diagnostic ultrasonic transducer

Item	Subject Device (SD)	Predicate Device (PD)
Regulation number	876.1500	876.1500
Product Code	ODG, ITX	FDF, ITX
Ultrasound Specifications		
Transducer Frequency	7-10 MHz (Nominal ultrasound frequencies of the transducer assembly)	7.5 MHz
Mode	Used with EU-ME3 B, PWD, Color Doppler, Combined, Other Aplio i800 B, M, PWD, Color Doppler, Combined, Other	Used with the SSD-5000 B, M, PWD, Color Doppler, Combined Used with EU-ME2 (combined in K203128) B, PWD, Color Doppler, Combined Used with EU-ME2 PREMIER PLUS (combined in K203128) B, PWD, Color Doppler, Combined, Other Used with EU-ME3 (combined in K243502) B, PWD, Color Doppler, Combined, Other Used with ALOKA ARIETTA850 (combined in K183456) B, M, PWD, Color Doppler, Combined, Other
Applicable Ultrasound system	OLYMPUS ENDOSCOPIC ULTRASOUND CENTER EU-ME3 Aplio i800	Aloka SSD-5000 OLYMPUS ENDOSCOPIC ULTRASOUND CENTER EU-ME2 (combined in K203128) OLYMPUS ENDOSCOPIC ULTRASOUND CENTER EU-ME2 PREMIER PLUS (combined in K203128) OLYMPUS ENDOSCOPIC ULTRASOUND CENTER EU-ME3 (combined in K243502) ALOKA ARIETTA 850 (combined in K183456)
Acoustic Output	I_{SPTA} :720 mW/cm^2 or less MI :1.9 or less	I_{SPTA} :720 mW/cm^2 or less MI :1.9 or less

Item	Subject Device (SD)	Predicate Device (PD)
Scanning Direction	Perpendicular to the insertion direction	Perpendicular to the insertion direction
Scanning Field of View [deg]	360	360
Axial resolution	1mm or less	1mm or less
Lateral resolution	3mm or less	3mm or less
Depth of penetration	Used with EU-ME3: 90mm or moreUsed with Aplio i800: 85mm or more	Not Provided
Scanning Method	Electronic radial array	Electronic radial array
Contact Method	Balloon method, sterile de-aerated water immersion method	Balloon method, sterile de-aerated water immersion method
Endoscope Specifications		
Field of View	100 ˚	100 ˚
Depth of Field	3 – 100 mm	3 – 100 mm
Direction of View	50˚ (forward-oblique)	55˚ (forward-oblique)
Optimum Working Distance	14 mm	14 mm
Type of CCD Chip	Color	Color
Total Number of Pixels	182,484	84,633
Pixels per square mm	226,757	—
Size of Pixel	2.1µm(H) x 2.1µm(V)	6.0µm(H) x 3.9µm(V)
Active Area of CCD Chip	865µm(H) x 857µm(V)	1414µm(H) x 1504µm(V)
Outer Diameter of Distal End	ø 13.4 mm	ø 13.8mm

Item	Subject Device (SD)	Predicate Device (PD)
Maximum distal end outer diameter	ø 14.7 mm	ø 15.0 mm
Outer Diameter of Insertion Tube	ø 10.9 mm	ø 11.8mm
Angulation UP/DOWN /LEFT/RIGHT [deg]	130/90/90/90	130/90/90/90
Working Length	1250 mm	1250 mm
Inner Diameter of Instrument Channel	Φ2.2mm	Φ2.2mm
Combination use with Electrosurgical instruments	Not applicable	Not applicable
NBI observation	Available	Not available
Distal end	Stainless	Stainless
A rubber adhesive	ES-8SC	ES-8SC
Ultrasound Cable	The ultrasound cable (MAJ-2056 or UITC-AI800A) is separated from ultrasound connector.	The ultrasound cable is combined with the endoscope.
Scope connector	Electrical connector is integrated to scope connector. Ultrasound connector is separated. When combined with the water-resistant cap, ultrasound connector is water resistant.	Electrical connector (transmit CCD image signal) and ultrasound connector are separated. When combined with the water-resistant cap, both connectors are water resistant.
Protect water penetration during reprocessing.	The US connector cap (MAJ-2295) is attached to the ultrasound cable connector on the endoscope to protect the ultrasound cable connector and the endoscope from water penetration during reprocessing.	Water resistant cap (MH-553) is attached to the electrical connector on the endoscope to protect the electrical connector and the endoscope from water penetration during reprocessing. Water resistant cap (MAJ-896) is attached to the ultrasound connector to protect from water penetration during reprocessing.

Item	Subject Device (SD)	Predicate Device (PD)
Sterilization methods for reprocessing endoscope	Ethylene oxide gas	Ethylene oxide gas
High-frequency accessories	Not available	Not available
RFID tag for communication with endoscope reprocessor	Available	Not available
Individual scope information (Scope ID)	Available	Not available

8. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination for GF-UE190:

1) Performance testing - Bench

Bench testing as listed below was conducted to ensure that the subject device performs as intended and meet design specifications.

- Thermal Safety
- Durability
- Dimensional Analysis
- Rates of Air, Water and Suction
- Photobiological Safety
- Endoscopic Image Field of View
- Endoscopic Image Direction of View
- Endoscopic Image Depth of Field
- Endoscopic Image Resolution
- Endoscopic Image Dynamic Range
- Endoscopic Image Signal to Noise Ratio
- Endoscopic Image Color Performance
- Endoscopic Image Intensity Uniformity
- Endoscopic Image Video Latency
- Endoscopic Image Distortion
- Acoustic Output
- Clinical Accuracy
- Elastography Function
- Shear Wave Speed Quantification Measurement
- Transducer Element Check

- Transportation and Storage

2) Performance testing - Animal

Animal testing was not performed.

3) Risk management

Risk management was performed in accordance with ISO 14971:2019. The design verification tests and their acceptance criteria were performed and identified as a result of this risk management.

9. CONCLUSIONS

Based on the indications for use, technological characteristics, performance testing and technological comparison to the predicate device, EVIS EUS ULTRASOUND GASTROINTESTINAL VIDEOSCOPE OLYMPUS GF-UE190 raises no new issue of safety and effectiveness and is substantially equivalent to the predicate device in terms of safety, effectiveness, and performance.