August 27, 2026

Olympus Medical Systems Corporation
% Brenda Geary
Director, Regulatory Affairs
Olympus Corporation of the Americas
800 W. Park Dr.
Westborough, Massachusetts 01581

Re: K260824
Trade/Device Name: Gastrointestinal Videoscope Olympus GIF-2T1500
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: FDS, NWB
Dated: July 28, 2026
Received: July 28, 2026

Dear Brenda Geary:

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.	K260824

Please provide the device trade name(s).

Gastrointestinal Videoscope Olympus GIF-2T1500

Please provide your Indications for Use below.

The GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-2T1500 is intended to be used with a video system center, documentation equipment, monitor, endoscopic therapy accessories (such as a biopsy forceps), and other ancillary equipment for endoscopy and endoscopic surgery. This instrument is indicated for use within the upper digestive tract (including the esophagus, stomach, and duodenum).

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

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

I. Submitter

Olympus Medical Systems Corporation
2951 Ishikawa-cho
Hachioji-shi
Tokyo 192-8507
Japan

Contact Person: Shinichiro Kawachi
Phone: +81 42-642-2111

Date Prepared: August 5, 2026

II. Device

Device Proprietary Names	Gastrointestinal Videoscope Olympus GIF-2T1500
Common or Usual Names	Endoscope
Classification Name	Endoscope and Accessories
Regulation Number	876.1500
Product Codes	FDS, NWB
Device Classification	Class II

III. Predicate Device

Substantial equivalence is claimed to the following device:

- FUJIFILM Endoscope Model EI-740D/S, K221551, Fujifilm Corporation

IV. Device Description

The Gastrointestinal Videoscope Olympus GIF-2T1500 (GIF-2T1500) is a non-sterile, reusable device, intended to be used with a video system center, documentation equipment, monitor, endoscopic therapy accessories (such as a biopsy forceps), and other ancillary equivalent for endoscopy and endoscopic surgery. The device is indicated for use within the upper digestive tract (including the esophagus, stomach, and duodenum).

The GIF-2T1500 features a CMOS (RGB color filter) image sensor and two (2) instrument channels (Ø 2.8 mm and 3.7 mm). The Ø 2.8 mm channel runs from the distal end to the connector and is used for inserting endoscopic accessories, introducing liquid from a syringe attached to the biopsy valve, or aspirating fluids, debris, or air from the lumen. The Ø 3.7 mm channel runs from the distal end to the instrument channel port of the control section and is used for inserting endoscopic accessories or introducing liquid from a syringe attached to the biopsy valve; this channel is not connected to the suction channel, therefore, cannot be used to aspirate the lumen. The endoscope consists of three parts: the insertion section, the control section, and the connector section.

The GIF-2T1500 is compatible with the EVIS X1 Video System Center (CV-1500).

The MAJ-420 Channel Connection Tube is a reprocessing accessory that attaches to the GIF-2T1500 instrument channel ports and is used to inject reprocessing fluids into both instrument channels of the endoscope. The tube can also be used to flush air through both channels to expel fluids.

V. Indications for Use

The GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-2T1500 is intended to be used with a video system center, documentation equipment, monitor, endoscopic therapy accessories (such as a biopsy forceps), and other ancillary equipment for endoscopy and endoscopic surgery. This instrument is indicated for use within the upper digestive tract (including the esophagus, stomach, and duodenum).

VI. Comparison of Technological Characteristics

The Gastrointestinal Videoscope Olympus GIF-2T1500 is substantially equivalent to the Endoscope Model EI-740D/S (K221551) as the subject and predicate devices have the same intended use and similar design and technological characteristics.

The subject device and predicate device are gastroscopes featuring the same direction of view and field of view, working length, and bending angulations. The devices include two instrument channels, and the distal ends are equipped with the same functions. Both endoscopes maintain records of device information and provide pre-freeze (anti-blur), electronic zoom, high frequency cauterization, and auxiliary water feeding functions.

When compared to the predicate device, the subject device utilizes a different image sensor (CMOS/RGB Color Filer vs. CCD) and has a slightly larger depth of field (2 - 100 mm vs 3 - 100 mm), a smaller overall diameter, and a longer total length (1350 mm vs. 1330 mm). Although the subject device's distal end outer diameter, maximum insertion section outer diameter, and insertion tube outer diameter are slightly smaller than those of the predicate device, they fall within the range of outer diameters for other legally marketed gastroscopes indicated for use in the upper digestive tract (e.g., K112680 and K232997). The subject device's first instrument channel has a smaller diameter (2.8 mm vs 3.2 mm) and Endo Therapy accessories enter and exit the subject device's endoscopic image from this channel at an angle. Although the subject device's first instrument channel diameter is smaller than that of the predicate device, it is the same diameter provided for other single channel gastroscopes indicated for use in the upper digestive tract (e.g., K112680). The subject device provides narrow-band imaging (NBI), red dichromatic imaging (RDI), and white light imaging (WLI) while the predicate device provides linked color imaging (LCI) and blue laser imaging (BLI). These technological differences do not raise different questions of safety and effectiveness when compared to the predicate device.

Validation of reprocessing instructions, a biological safety evaluation, software validation and cybersecurity testing, electrical safety and electromagnetic compatibility testing, and non-clinical testing, including comparative bench and animal studies were undertaken to demonstrate substantial equivalence to the predicate device.

VII. Performance Data

The following performance data were provided to demonstrate substantial equivalence of the GIF-2T1500:

- Reprocessing method validation per the FDA's Guidance for Industry and Food and Drug Administration Staff, "Reprocessing Medical Devices in Health Care Setting: Validation Methods and Labeling"
- Biocompatibility testing per ISO 10993-1:2018 including cytotoxicity (ISO 10993-5:2009), sensitization (ISO 10993-10:2021), irritation (ISO 10993-23:2021)
- Software verification and validation and cybersecurity testing per the FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" and "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices".
- Electrical safety and EMC testing per IEC 60601-1, IEC 60601-2-18, IEC 60601-1-2, and IEC TR 60601-4-2

- Mechanical testing and comparative testing to verify device performance
  - Durability
  - Thermal safety
  - Dimensional analysis
  - Photobiological safety
  - Transportation
  - Rates of air, water, and suction (Verification/Comparison)
  - Color performance
  - Field of View (FOV) and Direction of View (DOV)
  - Distortion (Verification/Comparison)
  - Resolution (Verification/Comparison)
  - Depth of Field (DOF)
  - Noise and dynamic range (Verification/Comparison)
  - Image Intensity Uniformity (Verification/Comparison)
  - Video Latency (Verification/Comparison)
  - Distal Attachment and Detachment
- An animal study was conducted to evaluate the performance of the Narrow Band Imaging (NBI) observation, TeXture and color enhancement Imaging (TXI), and Red Dichromatic Imaging (RDI) observation as well as the Brightness Adjustment Imaging with Maintenance of Contrast (BAI-MAC) function.

Clinical data is not required to demonstrate substantial equivalence.

VIII. Conclusion

The non-clinical data demonstrate that the subject devices are as safe, as effective, and perform as well as or better than the identified predicate devices. Therefore, it is concluded that the Gastrointestinal Videoscope Olympus GIF-2T1500 is substantially equivalent to the identified predicate device.