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: K260856
Trade/Device Name: Disposable Distal Attachment D-201-13404
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: FDS
Dated: July 29, 2026
Received: July 29, 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.	K260856

Please provide the device trade name(s).

Disposable Distal Attachment D-201-13404

Please provide your Indications for Use below.

The DISPOSABLE DISTAL ATTACHMENT D-201 Series have been designed to be attached to the distal end of the endoscope to keep the suitable depth of endoscope's view field within the gastrointestinal tract.

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
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Hachioji-shi
Tokyo 192-8507
Japan

Applicant Contact: Shinichiro Kawachi
Applicant Contant Phone: +81 42-642-2111

Primary Correspondent:
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Company: Olympus Corporation of the Americas
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Date Prepared: August 21, 2026

II. Device

Device Proprietary Names	Disposable Distal Attachment D-201-13404
Common or Usual Names	Endoscope and accessories
Classification Name	Gastroscope and Accessories, Flexible/Rigid
Regulation Number	876.1500
Product Codes	FDS
Device Classification	Class II

III. Predicate Device

Substantial equivalence is claimed to the following device:

- Disposable Distal Attachment D-201 Series, K250296, Olympus Medical Systems Corp.

IV. Device Description

The Disposable Distal Attachment Olympus D-201-13404 is a sterile (EO), single-use, short transparent tube which is attached to the distal end of a gastrointestinal videoscope to facilitate observation of tissues during endoscopic procedures. The distal attachment includes a drainage side hole that allows egress of water and blood during use.

V. Indications for Use

The DISPOSABLE DISTAL ATTACHMENT D-201 Series have been designed to be attached to the distal end of the endoscope to keep the suitable depth of endoscope's view field within the gastrointestinal tract.

VI. Comparison of Technological Characteristics

The Disposable Distal Attachment (D-201-13404) has the same intended use as the predicate device. The devices are intended to be attached to compatible endoscopes to keep the suitable depth of endoscope's view field within the gastrointestinal tract.

The Disposable Distal Attachment D-201-13404 is substantially equivalent to the Disposable Distal Attachment D-201 Series (K250296) as the subject and predicate devices have the same intended use and technological characteristics.

The subject device and predicate device are sterile, single-use, straight transparent tubes which are attached to the distal end of endoscopes using medical tape to maintain a suitable depth of the field of view during endoscopic procedures. A side drainage hole facilitates egress of fluids during endoscopic procedures. The purpose of the medical tape is to ensure that the distal attachment is secured to the endoscope. The medical tape is applied to the front side of the endoscope lens (insertion side); therefore, it does not impact the endoscopic field of view.

The outer diameter of the subject device falls within the outer diameter range of the predicate device, and the devices have the same length from the distal end of the endoscope.

Bench testing on the subject device specific to its use with the GIF-2T1500 (K260824 Under FDA review) was undertaken to verify compatibility with the endoscope.

VII. Non-Clinical and/or Clinical Tests Summary & Conclusions

Mechanical testing was conducted to verify endoscope durability against the attachment and detachment stress of the distal attachment and to assess the force needed to attach/detach the distal attachment to/from the endoscope.

Additional testing, from the Applicant's own predicate device, including biocompatibility testing, sterilization validation, EO residuals, packaging validation and shelf life testing, and non-clinical bench testing was leveraged.

The results of the non-clinical studies demonstrate substantial equivalence of the Disposable Distal Attachment D-201-13404 to the predicate device:

Clinical data is not required to demonstrate substantial equivalence.

VIII. Conclusion

The non-clinical data demonstrate that the subject device is as safe, as effective, and performs as well as or better than the identified predicate device. Therefore, it is concluded that the Disposable Distal Attachment D-201-13404 is substantially equivalent to the identified predicate device.