May 1, 2025

Olympus Medical Systems Corp.
% Roshana Ahmed
Program Manager, Regulatory Affairs
Olympus Corporation of the Americas
800 West Park Drive
Westborough, Massachusetts 01581

Re: K250296
Trade/Device Name: Disposable Distal Attachment D-201 Series
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: FDS, FDF
Dated: January 31, 2025
Received: January 31, 2025

Dear Roshana Ahmed:

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, PhD
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250296

Device Name

Disposable Distal Attachment D-201 Series

Indications for Use *(Describe)*

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.

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.

510(k) Summary

I. Submitter

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

Contact Person: Seiko Yunoki
Phone: +81 42-642-2111

Date Prepared: January 20, 2025

II. Device

Device Proprietary Name	Disposable Distal Attachment D-201 Series
Common or Usual Name	Distal Attachment
Classification Name	Endoscope and accessories
Regulation Number	876.1500
Product Code	FDS/FDF
Device Classification	Class II

III. Predicate Device

Substantial equivalence is claimed to the following device:

- Olympus Distal Attachment, MODELS MH-462, -463, -464, -465, -466, -483, -587, -588, -589, -590, -591, -592, -593, -594, -595, -596, -597, -598, K984358, Olympus America, Inc.

IV. Device Description

The Disposable Distal Attachment D-201 Series is comprised of seven (7), sterile, single-use, distal attachments of varying diameters. Each distal attachment is a short transparent

plastic tube which is attached to the distal end of an endoscope to facilitate observation of tissues during endoscopic procedures. A subset of the models includes a drainage side hole that allows egress of water and blood during use.

The Disposable Distal Attachment D-201 Series is to be used with compatible endoscopes.

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 subject device 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 subject device and predicate device are 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. Except for variant D-201-11802, the subject device includes a side drainage hole to facilitate egress of fluids during endoscopic procedures. Furthermore, the subject device is provided sterile (via EtO) and is intended for single use. The subject and predicate device are offered in similar outer diameters; however, the subject device features a shorter length from the distal end of the endoscope than the predicate device.

Bench testing, biological safety evaluation, sterilization validation, and shelf-life studies were undertaken on the subject device and predicate device to demonstrate substantial equivalence. A comparison of the subject and predicate device technological characteristics is provided below.

	Subject Device **Disposable Distal Attachment D-201 Series**	**Predicate Device** **Distal attachment MH series**	**Analysis**
Manufacturer	Olympus Medical Systems Corp.	Olympus Medical Systems Corp.	-
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.	Olympus Distal Attachment has been designed to be attached to the distal end of the endoscope to facilitate endoscopic therapy. Olympus Distal Attachment is used for the followings 1.Gastrointestinal mucosal resection (endoscopic mucosal resection) 2.Keeping the suitable depth of endoscope's view field 3.Helping the endoscope with being inserted into the gastrointestinal tract	Substantially equivalent
Models	D-201-10704 D-201-11304 D-201-11804 D-201-12704 D-201-14304 D-201-15004 D-201-11802	MH-463 MH-598	Substantially equivalent
Type	Straight	MH-463: Straight MH-598: Straight with rim	Substantially equivalent
Outer diameter	Ø 11.35 – 15.7 mm	MH-463: Ø 13.5 mm MH-598: Ø 19.2 mm	Substantially equivalent
Drainage Side Holes	Yes D-201-10704 D-201-11304 D-201-11804 D-201-12704 D-201-14304 D-201-15004	-	Different
	No D-201-11802	No	Identical
Attachment to endoscope	Medical tape	Medical tape	Identical

	Subject Device Disposable Distal Attachment D-201 Series	Predicate Device Distal attachment MH series	Analysis
Single use/Re-usable	Single use	Reusable	Different
Sterile/non-sterile	Sterile	Non-sterile	Different
Sterilization method	ETO	Non sterilized (Autoclave by the user before use)	Different
Transparent	Yes	Yes	Identical
Biocompatible	Yes ISO 10993-1:2018	Yes ISO 10993-1	Identical

VII. Performance Data

The following performance data were provided to demonstrate substantial equivalence:

- Biocompatibility testing per ISO 10993-1:2018 including cytotoxicity (ISO 10993-5:2009), sensitization (ISO 10993-10:2021), irritation (ISO 10993-23:2021), acute systemic toxicity (ISO 10993-11:2017), and material mediated pyrogenicity (USP <51>)
- Sterilization validation per ISO 11135:2014
- Ethylene oxide residuals per ISO 10993-7:2008
- Packaging validation and shelf life testing in accordance with ISO 11607-1:2019 and ASTM F1980-21
- Mechanical testing and comparative testing to verify device performance
- Human Factors Testing

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 Series is substantially equivalent to the identified predicate device.