March 6, 2026

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

Re: K251807
Trade/Device Name: Single Use Electrosurgical Hemostatic Forceps FD-410LR, FD-411UR, FD-412LR
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic Electrosurgical Unit And Accessories
Regulatory Class: Class II
Product Code: KGE
Dated: February 5, 2026
Received: February 5, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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,

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

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.	K251807

Please provide the device trade name(s).

Single Use Electrosurgical Hemostatic Forceps FD-410LR, FD-411UR, FD-412LR

Please provide your Indications for Use below.

Models FD-410LR & FD-412LR:
The Single Use Electrosurgical Hemostatic Forceps FD-410LR/412LR are intended to be used to cauterize and coagulate or perform hemostasis using high-frequency current within the upper digestive tract in combination with an endoscope.

Model FD-411UR:
The Single Use Electrosurgical Hemostatic Forceps FD-411UR is intended to be used to cauterize and coagulate or perform hemostasis using high-frequency current within the lower digestive tract in combination with an endoscope.

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

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

510(k) Summary (K251807)

I. Submitter

Olympus Medical Systems Corporation
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Hachioji-shi
Tokyo 192-8507
Japan

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

Date Prepared: February 6, 2026

II. Device

Device Proprietary Name	Single Use Electrosurgical Hemostatic Forceps FD-410LR, FD-411UR, FD-412LR
Common or Usual Name	Electrosurgical Hemostatic Forceps
Classification Name	Endoscopic Electrosurgical Unit and Accessories
Regulation Number	876.4300
Product Code	KGE
Device Classification	Class II

III. Predicate Device

Substantial equivalence is claimed to the following device:

- Ensure Single-Use Coagulation Forceps, K202438, Micro-Tech (Nanjing) Co., Ltd.

IV. Device Description

The Electrosurgical Hemostatic Forceps FD-400 series is comprised of three (3), sterile, single-use, electrosurgical hemostatic forceps of varying forceps opening widths (4 – 6.5 mm). The subject device was designed to be used with compatible endoscopes to cauterize and coagulate or to perform hemostasis using high-frequency current in the upper (Models FD-410LR and FD-412LR) and lower digestive tract (FD-411UR).

The hemostatic forceps are attached to an electrosurgical unit via an A-cord to deliver high-frequency current to cauterize and coagulate or to perform hemostasis on the target tissue. The forceps are manufactured from stainless steel.

The Electrosurgical Hemostatic Forceps FD-400 series is to be used with compatible electrosurgical units, A cords, and endoscopes.

V. Indications for Use

The Single Use Electrosurgical Hemostatic Forceps FD-410LR/412LR are intended to be used to cauterize and coagulate or perform hemostasis using high-frequency current within the upper digestive tract in combination with an endoscope.

The Single Use Electrosurgical Hemostatic Forceps FD-411UR is intended to be used to cauterize and coagulate or perform hemostasis using high-frequency current within the lower digestive tract in combination with an endoscope.

VI. Comparison of Technological Characteristics

The subject device has the same intended use as the predicate device. The devices are intended to cauterize and coagulate or perform hemostasis using high-frequency current within the digestive tract in combination with an endoscope.

The subject device and predicate device are single-use, sterile (ETO), electrosurgical hemostatic forceps featuring rotating distal ends and the same working length.

The subject device differs from the predicate device with respect to the shape and opening width of the cups, maximum outer diameter, channel inner diameter, and rated high frequency voltage. As verified through bench testing, these differences do not affect the performance of the device when compared to the predicate.

Bench testing, biological safety evaluation, sterilization validation, and shelf-life studies were undertaken on the subject device to demonstrate substantial equivalence. Detailed information regarding the studies is provided within the submission.

A comparison of the subject and predicate device technological characteristics is provided below.

	Subject Device **Single Use Electrosurgical Hemostatic Forceps FD-410LR, FD-411UR, FD-412LR**	**Predicate Device** **Ensure Single-Use Coagulation Forceps**
Indications for use	The Single Use Electrosurgical Hemostatic Forceps FD-410LR/412LR are intended to be used to cauterize and coagulate or perform hemostasis using high-frequency current within the upper digestive tract in combination with an endoscope. The Single Use Electrosurgical Hemostatic Forceps FD-411UR is intended to be used to cauterize and coagulate or perform hemostasis using high-frequency current within the lower digestive tract in combination with an endoscope.	These instruments have been designed to be used with endoscopes to cauterize and coagulate or to perform hemostasis using high-frequency current within the digestive tract.
Cup Opening Width	FD-410LR: 5 mm FD-411UR: 4 mm FD-412LR: 6.5 mm	Type B: 6.3 mm
Maximum Outer Diameter	FD-410LR, FD-412LR: 2.75 mm FD-411UR: 3.1 mm	≤ 2.7 mm
Rotate Function	Yes	Yes
Rated high frequency voltage	COAG: 2900 Vp (5800 Vp-p)	COAG: 2300 Vp (4600 Vp-p)
Single use/Re-usable	Single use	Single use
Sterile/non-sterile	Sterile	Sterile
Sterilization method	ETO	ETO

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, ISO 11607-7:2019, and ASTM F1980-21
- Electrical safety and EMC testing per IEC 60601-1, IEC 60601-1-2, and IEC TR 60601-4-2
- Mechanical testing and comparative testing to verify device performance
    - Opening and closing
    - Device reliability
    - Insertion and withdrawal
    - Advancing and retreating
    - Rotation
    - Durability
    - Resistance
- Coagulation and Hemostasis 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 Single Use Electrosurgical Hemostatic Forceps FD-410LR, FD-411UR, FD-412LR is substantially equivalent to the identified predicate device.