October 7, 2025

Olympus Medical Systems Corporation
℅ Susan Lewandowski
Program Manager, Regulatory Affairs
Olympus Surgical Technologies of America
800 West Park Drive
Westborough, Massachusetts 01581

Re: K250187
Trade/Device Name: Disposable Hot Biopsy Forceps (FD-210U); Disposable Hot Biopsy Forceps (FD-230U)
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic Electrosurgical Unit And Accessories
Regulatory Class: Class II
Product Code: KGE
Dated: September 5, 2025
Received: September 5, 2025

Dear Susan Lewandowski:

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
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)*

K250187

Device Name

Disposable Hot Biopsy Forceps (FD-210U);
Disposable Hot Biopsy Forceps (FD-230U)

Indications for Use *(Describe)*

The DISPOSABLE HOT BIOPSY FORCEPS FD-210U/FD-230U are intended to be used to collect tissue samples within the digestive tract using high-frequency current under endoscopic observation in combination with an endoscope.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

1. General Information

Date Prepared: September 5, 2025

510(K) submitter: **Olympus Medical Systems Corporation**
2951 Ishikawa-cho, Hachioji-shi, Tokyo Japan 192-8507

Contact: Seiko Yunoki
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Correspondent: Olympus Surgical Technologies of America
800 West Park Drive, Westborough, MA 01581

Primary Contact: Susan Lewandowski
Email: susan.lewandowski@olympus.com

2. Device Information

Device Name: Disposable Hot Biopsy Forceps FD-210U/FD-230U
Model Name: DISPOSABLE HOT BIOPSY FORCEPS FD-210U/FD-230U
Common Name: Biopsy Forceps
Classification: 876.4300 – Endoscopic electrosurgical unit and accessories
Regulatory Class: II
Product Code: KGE – Forceps, Biopsy, Electric
Device Panel: Gastroenterology & Urology

3. Predicate Device Information

Device Name	510(k) Submitter	510(k) Number
Radial Jaw 4 Hot Biopsy Forceps	Boston Scientific Corp.	K101657

4. Device Description

The Disposable Hot Biopsy Forceps have been designed to collect tissue endoscopically within the digestive tract using high-frequency current under endoscopic observation. The Disposable Hot Biopsy Forceps consists of a handle section and insertion portion. The cups in the distal end of insertion portion are activated in the open and closed

position by maneuvering the slider in the handle. The cup shapes are provided in either alligator jaw-step (FD-210U) or oval type (FD-230U).

The subject device is connected to a compatible electrosurgical device by an A-cord. The A-cord jack is connected to the plug on the handle of the subject device. The target tissue is held by the cups. The tissue is subjected to high frequency electric current transmitted from the plug which allows for collecting tissue.

The subject device has the same technological characteristics and similar design as the applicable predicate device.

5. Indications for Use

The DISPOSABLE HOT BIOPSY FORCEPS FD-210U/FD-230U are intended to be used to collect tissue samples within the digestive tract using high frequency current under endoscopic observation in combination with an endoscope.

6. Predicate Comparison

Item	**Subject Device**	**Predicate Device**	**Comments on Difference**
	DISPOSABLE HOT BIOPSY FORCEPS FD-210U/FD-230U	**Radial Jaw 4 Hot Biopsy Forceps**	
		K101657	
Manufacturer	OLYMPUS MEDICAL SYSTEMS CORP.	Boston Scientific Corp.	
Indications for Use	The DISPOSABLE HOT BIOPSY FORCEPS FD-210U/FD-230U are intended to be used to collect tissue samples within the digestive tract using high-frequency current under endoscopic observation in combination with an endoscope.	These Single-Use Hot Biopsy Forceps are intended to be used through an endoscope to cauterize and remove polys and/or tissue specimens throughout the alimentary tract. The alimentary tract includes the esophagus	Similar - Both use high frequency current to remove tissue from the digestive tract.
Single-Use/Reuse	Single Use	Single Use	Same as the predicate device
Sterilization	Gamma-ray radiation	Gamma-ray radiation	Same as the predicate device
Working Length	2300mm	2400mm	Similar – The differences in dimensions/cup shape do not impact the safety or effectiveness as demonstrated by Performance Testing.
Maximum Insertion Portion Diameter	2.45mm	2.75mm	
Shape of Cups	FD-210U – Alligator jaw-step FD-230U – Oval Type	Alligator jaw-step	
Cup Diameter	2.2mm	2.2mm	Same

7. Non-Clinical/Clinical Tests Summary and Conclusion

Olympus performed non-clinical testing to demonstrate substantial equivalence to the predicate device. Test samples were final, finished devices subjected to the full manufacturing process including sterilization.

The following performance bench tests were conducted to demonstrate substantial equivalence between the subject and predicate devices. All test samples passed pre-defined acceptance criteria.

- Forceps Opening and Closing
- Insertion Into and Withdrawal from an Endoscope
- Device Reliability
- Advancing and Retreating Against the Endoscope
- Connection of A-Cord
- Cup Durability
- Tissue Collection Performance

The following testing was also conducted.

- Sterilization and Shelf-Life
- Biocompatibility

8. Conclusion

Based on the comparison to the predicate device, intended use, technological characteristics, and performance testing, the Disposable Hot Biopsy Forceps raise no new issues of safety and effectiveness and are substantially equivalent to the predicate device in terms of safety, efficacy, and performance.