May 30. 2025

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

Re: K250957
Trade/Device Name: Disposable Biopsy Forceps (FB-211D); Disposable Biopsy Forceps (FB-221D); Disposable Biopsy Forceps (FB-231D); Disposable Biopsy Forceps (FB-241D)
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (flexible or rigid) and accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: March 30, 2025
Received: March 31, 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,

Ethan L. Nyberg -S

Ethan Nyberg, Ph.D.
Assistant Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental 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.	K250957

Please provide the device trade name(s).

Disposable Biopsy Forceps (FB-211D);
Disposable Biopsy Forceps (FB-221D);
Disposable Biopsy Forceps (FB-231D);
Disposable Biopsy Forceps (FB-241D)

Please provide your Indications for Use below.

The DISPOSABLE BIOPSY FORCEPS FB-211D/221D/231D/241D are intended to be used to collect tissue within the tracheobronchial tree in combination with a bronchoscope

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

1. General Information

Date Prepared: May 27, 2025

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

Contact: Seiko Yunoki

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 Biopsy Forceps FB-211D
Disposable Biopsy Forceps FB-221D
Disposable Biopsy Forceps FB-231D
Disposable Biopsy Forceps FB-241D

Common Name: Biopsy Forceps
Classification: 874.4680 Bronchoscope (flexible or rigid) and accessories
Regulatory Class: II
Product Code: EOQ
Device Panel: Ear, Nose, & Throat

3. Predicate Device Information

Olympus Single Use Biopsy Forceps FB-433D – K172726

4. Device Description

The Disposable Biopsy Forceps FB-211D, FB-221D, FB-231D, and FB-241D (also known as “EndoJaw”) have been designed to collect tissue within the tracheobronchial tree in combination with a flexible bronchoscope. The Disposable Biopsy Forceps are inserted into the channel of a bronchoscope to collect tissue by biting the surface of the lesion with a pair of forceps located at the distal end of the device. The Disposable Biopsy Forceps are withdrawn from the channel and the tissue sample is collected.

The Disposable Biopsy Forceps consists of a handle and an insertion portion. The handle consists of a handle body and slider. The insertion portion consists of a sheath, metallic coil

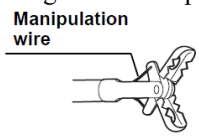
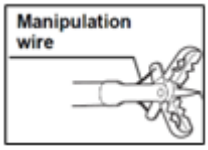
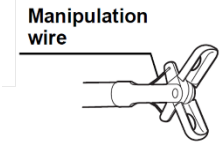
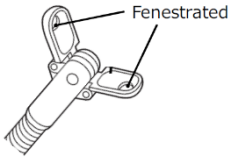
(operating wire), cups, and forceps cap. The slider is connected to the operating wire in the insertion portion and the cups are opened/closed by advancing/retreating the slider with the function of the connection parts. The subject device is available in multiple distal end cup shapes; FB-211D – Alligator jaw-step, FB-221D – Alligator jaw-step with needle, FB-231D – Oval type, and FB-241D – Oval type with needle.

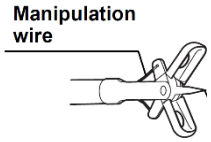
The subject device has the same technological characteristics and similar design as the applicable predicate device.

5. Indications for Use

The DISPOSABLE BIOPSY FORCEPS FB-211D/FB-221D/FB-231D/FB-241D are intended to be used to collect tissue within the tracheobronchial tree in combination with a bronchoscope.

6. Predicate Comparison

Description	Subject Device (SD) Single Use Biopsy Forceps FB-211D, FB-221D, FB-231D, and FB-241D	Predicate Device (PD) Single Use Biopsy Forceps FB-433D (K172726)	Comparison
Design of Insertion portion of Forceps	The insertion portion is a stainless steel coil covered by a polyethylene sheath.	The insertion portion is a stainless steel coil.	DIFFERENT Non-clinical bench testing was performed to demonstrate that this difference in technology does not impact the effectiveness of the device.
Cup Shape	FB-211D Alligator Jaw-step  FB-221D Alligator jaw-step with needle  FB-231D Oval type  FB-241D	Standard (Oval type), Fenestrated 	SIMILAR Non-clinical bench testing was performed to demonstrate that design differences between the subject and predicate devices do not impact the performance of the subject device.

Description	Subject Device (SD) Single Use Biopsy Forceps FB-211D, FB-221D, FB-231D, and FB-241D	Predicate Device (PD) Single Use Biopsy Forceps FB-433D (K172726)	Comparison
	Oval type with Needle 		
Compatible Endoscopes	Bronchoscopes with channel diameter 2.0 mm and working length 600 mm or less (exclude ultrasound endoscopes).	Bronchoscopes with channel diameter 1.7 mm and working length 600 mm or less (exclude ultrasound endoscopes).	SIMILAR There is a difference in the compatible endoscope channel diameter between the SD and PD. Non-clinical bench testing was performed to demonstrate that design differences between the subject and predicate devices do not impact the performance of the subject device.
Product Specifications	Maximum insertion portion diameter: 1.9 mm Working length: 1150 mm	Maximum insertion portion diameter: 1.5 mm Working length: 1150 mm	SIMILAR There is a difference in the maximum insertion portion channel diameter between the SD and PD. Non-clinical bench testing was performed to demonstrate that design differences between the subject and predicate devices do not impact the performance of the subject device.
Single Use/Reusable	Single Use	Single Use	SAME
Sterilization	Gamma	Ethylene Oxide (EtO)	DIFFERENT There is a difference in sterilization methods between the SD and PD. Sterilization validation testing was performed to demonstrate the efficacy of the sterilization dose.
Shelf-Life	Five years	Three years	DIFFERENT There is a difference in shelf-life expiry dating between the SD and PD.

Description	Subject Device (SD) Single Use Biopsy Forceps FB-211D, FB-221D, FB-231D, and FB-241D	Predicate Device (PD) Single Use Biopsy Forceps FB-433D (K172726)	Comparison
			Stability / Shelf-life testing was performed to demonstrate the difference does not impact the effectiveness of the subject device.

7. Non-Clinical/Clinical Tests Summary and Conclusion

Olympus performed bench 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 side-by-side bench tests were conducted to demonstrate substantial equivalence between the subject and predicate devices. All test samples passed pre-defined acceptance criteria.

- Insertion Performance into the Bronchoscope
- Withdrawal Performance from the Bronchoscope
- Opening and Closing of the Forceps Cups
- Visual Inspection of the Insertion Portion
- Performance After Repeated Insertion and Withdrawal Operations
- Performance After Repeated Open/Close Operations
- Connection Strength Between the S-Cover and the Coil Sheath
- Visual Inspection for Defects of the Needle and Forceps Teeth

8. Biocompatibility Testing

Biocompatibility testing for the Disposable Biopsy Forceps was conducted in accordance with the FDA's Guidance for Industry and Food and Drug Administration Staff, Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process." The biocompatibility testing included cytotoxicity, sensitization, irritation, acute systemic toxicity, and material mediated pyrogenicity.

9. Sterilization and Shelf Life

The devices are sterilized via gamma radiation. Sterilization validation (VDmax25) was conducted in accordance with ISO 11137-1:2006/Amd1:2013 and Amd2:2018 Sterilization of Health Care Product – Radiation Part 1 – Requirements for development, validation and routine control of a sterilization process for medical devices and ISO11137-2:2013 Sterilization of Health Care Product – Radiation Part 2 – Establishing the sterilization dosage . The sterility assurance level is 10^{-6}.

The shelf-life of the subject device is five years. Olympus conducted stability testing to demonstrate packaging integrity and product performance for the stated expiration date. The accelerated aging test was conducted in accordance with ASTM F1980-21. Package integrity testing was conducted in accordance with ASTM F1980-21, ISO 11607-1:2019 and ISO 11607-2:2019 after accelerated aging and simulated distribution. Package Integrity testing included Visual Inspection of Package, Peel Strength of Package, and Integrity of the Package. All samples successfully met the acceptance criteria and passed testing.

10. Human Factors Testing

Olympus conducted a Human Factors Evaluation and determined that the Disposable Biopsy Forceps FB-series are safe for intended users, uses, and use environments.

11. Conclusion

Based on the comparison to the predicate device, intended use, technological characteristics, and performance testing, the Disposable Biopsy Forceps FB-211D, FB-221D, FB-231D, and FB-241D are substantially equivalent to the predicate device.