March 20, 2026

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

Re: K252050
Trade/Device Name: Disposable Biopsy Forceps FB-211D, FB-221D, FB-231D, FB-241D
Regulation Number: 21 CFR 874.4760
Regulation Name: Nasopharyngoscope (flexible or rigid) and accessories
Regulatory Class: Class II
Product Code: EOB
Dated: February 17, 2026
Received: February 17, 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 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,

JOYCE C. LIN -S

for Shu-Chen Peng, Ph.D.
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K252050

Device Name
Disposable Biopsy Forceps FB-211D, FB-221D, FB-231D, FB-241D

Indications for Use *(Describe)*
The Disposable Biopsy Forceps FB-211D/221D/231D/241D are intended to be used to collect tissue within the upper airways in combination with a rhino-laryngoscope.

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.

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510(k) Summary

I. Submitter

Olympus Medical Systems Corporation
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Tokyo 192-8507
Japan

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

Date Prepared: July 11, 2025

II. Device

Device Proprietary Name	Disposable Biopsy Forceps FB-211D, FB-221D, FB-231D, FB-241D
Common or Usual Name	Biopsy Forceps
Classification Name	Nasopharyngoscope (flexible or rigid) and accessories
Regulation Number	874.4760
Product Code	EOB
Device Classification	Class II

III. Predicate Device

Substantial equivalence is claimed to the following device:

- Biopsy Forceps FB-56D-1, K013591, Olympus Optical Co., Ltd.

The following device is referenced within the submission:

- Disposable Biopsy Forceps FB-211D, FB-221D, FB-231D, FB-241D, K250957, Olympus Medical Systems Corporation

IV. Device Description

The Disposable Biopsy Forceps FB Series is comprised of four (4), sterile, single-use, disposable biopsy forceps of varying distal fenestrated 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 Disposable Biopsy Forceps FB Series was designed to collect tissue within the upper airways when used in conjunction with compatible rhino-laryngoscopes to collect tissues in the upper airways. The Disposable Biopsy Forceps FB Series consists of a handle and an insertion portion. The handle consists of a handle body and slider. The insertion portion consists of a covered coil sheath (stainless steel coil operating wire and polyethylene sheath), 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.

V. Indications for Use

The Disposable Biopsy Forceps FB-211D/221D/231D/241D are intended to be used to collect tissue within the upper airways in combination with a rhino-laryngoscope.

VI. Comparison of Technological Characteristics

Although there are slight differences between the subject device and predicate device indications for use statements, both products have the same intended use. The devices are intended to collect tissue from the upper airways when used in conjunction with a rhino-laryngoscope.

The subject device and predicate device are sterile, single-use biopsy forceps featuring the same working length. The subject device differs from the predicate device with respect to the shape of the cups (distal end), maximum insertion portion diameter, compatible endoscopes, and sterilization method.

Bench testing studies were undertaken on the subject device to demonstrate substantial equivalence. Detailed information regarding the studies is provided within the submission. Packaging validation, sterilization validation, and biocompatibility studies conducted on the subject device and submitted under K250957 are being leveraged to support demonstration of substantial equivalence.

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

	Subject Device Disposable Biopsy Forceps FB Series	Predicate Device Biopsy Forceps FB-56D-1	Analysis
Manufacturer	Olympus Medical Systems Corp.	Olympus Optical Co., Ltd.	-
Indications for use	The Disposable Biopsy Forceps FB-211D/221D/231D/241D are intended to be used to collect tissue within the upper airways in combination with a rhino-laryngoscope.	These instruments have been designed to be used with an Olympus endoscope to collect tissue within the nasal and nasopharyngeal lumen.	Substantially equivalent
Models/Shape of Cup	FB-211D/Alligator jaw-step FB-221D/Alligator jaw-step with needle FB-231D/Oval type FB-241D/Oval type with needle	FB-56D-1/Rat tooth	-
Maximum Insertion Portion Diameter	Ø 1.9	Ø 1.15	Substantially equivalent
Working Length	1150 mm	1150 mm	Identical
Compatible Endoscope	Working length less than 600 mm; BF, ENF Channel Inner Diameter [mm]: ø2.0, ø2.2, ø2.6, ø2.8, ø3.2	Working length less than 700 mm; CHF, BF, URF, HYF Channel Inner Diameter [mm]: ø1.2	Substantially equivalent
Single use/Re-usable	Single use	Reusable	Substantially equivalent
Sterile/non-sterile	Sterile	Sterile	Substantially equivalent
Sterilization method	Gamma radiation	Autoclave	Substantially equivalent

VII. Performance Data

The following performance data were provided to demonstrate substantial equivalence:

- Shelf life testing in accordance with ISO 11607-1:2019 and ASTM F1980-21
- Mechanical testing and comparative testing to verify device performance
  - Insertion performance
  - Withdrawal performance
  - Opening and closing
  - Advance and retreat
  - Performance after repeated operations
  - Connection strength
  - Visual inspection
  - Slider mechanism performance
- Human Factors Testing

The following data from the Applicant's own reference device is leveraged 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 11137
- Packaging validation in accordance with ISO 11607-1:2019 and ASTM F1980-21

Animal and clinical study data are 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 the identified predicate device. Therefore, it is concluded that the Disposable Biopsy Forceps FB Series is substantially equivalent to the identified predicate device.