March 31, 2025

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

Re: K250263
Trade/Device Name: Disposable Grasping Forceps FG-52D/FG-54D
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: KTI
Dated: January 28, 2025
Received: January 29, 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,

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

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.

510(k) Number *(if known)*
K250263

Device Name
Disposable Grasping Forceps FG-52D/54D

Indications for Use *(Describe)*

The Disposable Grasping Forceps FG-52D/54D are intended to be used to retrieve foreign bodies, calculus or tissue specimens from the tracheobronchial tree 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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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: March 28, 2025

II. Device

Device Proprietary Name	Disposable Grasping Forceps FG-52D/FG-54D
Common or Usual Name	Grasping Forceps
Classification Name	Bronchoscope (flexible or rigid) and accessories
Regulation Number	874.4680
Product Code	KTI
Device Classification	Class II

III. Predicate Device

Substantial equivalence is claimed to the following device:

- Microvasive Zero Tip Airway Retrieval Basket, Models M00513200 and M00513210, K020765, Boston Scientific Corp.

IV. Device Description

The Disposable Grasping Forceps FG-52D/FG-54D are designed to retrieve foreign bodies, calculus, or tissue specimens endoscopically within the tracheobronchial tree when used in conjunction with a compatible endoscope.

Each device is provided sterile and consists of a handle and an insertion portion. The handle (proximal portion) of the Disposable Grasping Forceps includes a ring which can be pushed or pulled to open or close the grasping portion of the device. The distal end of the insertion portion consists of the grasping portion of the device. The grasping portion, manufactured from stainless steel, is provided in two shapes: spiral basket type (model FG-52D) and three nail type (model FG-54D) and has limited contact with the patient. The user will select the device model depending on procedural needs.

V. Indications for Use

The Disposable Grasping Forceps FG-52D/54D are intended to be used to retrieve foreign bodies, calculus or tissue specimens from the tracheobronchial tree in combination with an endoscope.

VI. Comparison of Technological Characteristics

There are slight differences between the subject device and predicate device indications for use statements; however, these differences do not create a new intended use with respect to the subject device. The subject and predicate devices are both used in conjunction with scopes to remove materials from the tracheobronchial tree.

The subject device and predicate devices are sterile (via EtO), single use devices which are used with compatible endoscopes. A comparison of the subject and predicate device technological characteristics is provided below.

	Disposable Grasping Forceps FG-52D/FG-54D	**Microvasive® Zero Tip™ Airway Retrieval Basket**	**Analysis**
Manufacturer	Olympus Medical Systems Corp.	Boston Scientific Corp.	N/A
Indications for Use Statement	The Disposable Grasping Forceps FG-52D/54D are intended to be used to retrieve foreign bodies, calculus or tissue specimens from the tracheobronchial tree in combination with an endoscope.	The Microvasive® Zero Tip™ Airway Retrieval Basket is used to access the airway tree via a bronchoscope for the purpose of removing foreign bodies.	Substantially equivalent
Models	FG-52D FG-54D	M00513200	N/A

	Disposable Grasping Forceps FG-52D/FG-54D	Microvasive® Zero Tip™ Airway Retrieval Basket	Analysis
Maximum Insertion Portion Diameter	FG-52D: 0.8 mm FG-54D: 1.05 mm	M00513200: 0.8 mm	Substantially equivalent
Working Length	1150 mm	1200 mm	Substantially equivalent
Opening Width	FG-52D: 8 mm FG-54D: 10 mm	M00513200: 12 mm	Substantially equivalent
Shape of the Grasping Portion	FG-52D: Spiral Basket Type FG-54D: Three Nail Type	M00513200: Basket Type	Substantially equivalent
Compatible Endoscopes	Model and length: working length less than 700 mm (BF) Channel inner diameter: Ø 1.2, 2.0, 2.2, 2.6, 2.8, 3.2	Unknown	Substantially equivalent
Sterilization	Ethylene Oxide	Ethylene Oxide	Identical
Single-Use/ Reusable	Single Use	Single Use	Identical

The subject and predicate devices differ as follows:

- The subject device (model FG-54D) has a larger maximum insertion portion diameter than the predicate device.
- The working length of the subject device is slightly shorter than the working length of the predicate device.
- The opening width of the subject device is smaller than the opening width of the predicate device.
- The shape of the grasping portion of the subject device (model FG-54D) is different than the grasping portion of the predicate device.
- The subject devices are compatible with endoscopes featuring a working length of 700 mm (BF) and a channel inner diameter ranging from 1.2 – 3.2.

The differences in insertion portion diameter, working length, opening width, shape of the grasping portion, and compatible endoscopes do not raise different questions of safety or effectiveness when comparing the subject device to the predicate device. These differences are addressed through bench testing of the subject and predicate device.

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 <151>)
- 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 F1980-16
- Mechanical testing and comparative testing to verify device performance:
    - Insertion force/ Withdrawal force
    - Handle Operation
    - Grasping Performance
    - Strength Testing of the Connection and Distal Tip
    - Device Reliability
    - 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 Grasping Forceps FG-52D/FG-54D are substantially equivalent to the identified predicate device.