December 17, 2020

Olympus Medical Systems Corp.
% Sheri Musgnung
Regulatory Affairs Manager
Olympus Corporation of the Americas
3500 Corporate Parkway PO Box 610
Center Valley, Pennsylvania 18034-0610

Re: K200342
Trade/Device Name: Single Use Grasping Forceps FG-214P, Single Use Grasping Forceps FG-220P, Single Use Grasping Forceps FG-226C, Single Use Grasping Forceps FG-232L, Single Use Grasping Forceps FG-804L
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOQ, EOB
Dated: November 18, 2020
Received: November 18, 2020

Dear Sheri Musgnung:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

for Malvina B. Eydelman, M.D.
Director
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200342

Device Name
Single Use Grasping Forceps FG-214P, FG-804L

Indications for Use *(Describe)*

This instrument has been designed to be used with an Olympus endoscope to retrieve foreign bodies or resected tissue from the nasal lumens and airway anatomy (including nasopharynx and trachea).

This instrument has been designed to be used with an Olympus endoscope to retrieve foreign bodies or resected tissue from the airways and tracheobronchial tree.

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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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
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See PRA Statement below.

510(k) Number *(if known)*
K200342

Device Name
Single Use Grasping Forceps FG-226C, FG-232L

Indications for Use *(Describe)*
This instrument has been designed to be used with an Olympus endoscope to retrieve foreign bodies or resected tissue from the airways and tracheobronchial tree.

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)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200342

Device Name
Single Use Grasping Forceps FG-220P

Indications for Use *(Describe)*
This instrument has been designed to be used with an Olympus endoscope to retrieve foreign bodies from the nasal lumens and airway anatomy (including nasopharynx and trachea).

This instrument has been designed to be used with an Olympus endoscope to retrieve foreign bodies from the airways and tracheobronchial tree.

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)

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December 17, 2020
K200342

510(k) Summary

1. GENERAL INFORMATION

■ 510(k) Submitter: OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho, Hachioji-shi, Tokyo, 192-8507, Japan

■ Contact Person: Sheri L. Musgnung
Olympus Corporation of the Americas
3500 Corporate Parkway PO Box 610
Center Valley, PA 18034-0610, USA
Phone: 484-896-3147
Fax: 484-896-7128
Email: sheri.musgnung@olympus.com

■ Manufacturing site: Aomori Olympus Co., Ltd.
2-248-1 Okkonoki, Kuroishi-shi, Aomori 036-0357, Japan

2. DEVICE IDENTIFICATION

Device Name	Model Name	Regulation Number/Name	Product Code
Single Use Grasping Forceps FG-214P	FG-214P	874.4680 Bronchoscope (flexible or rigid) and accessories 876.4760 Nasopharyngoscope (flexible or rigid) and accessories	EOQ EOB
Single Use Grasping Forceps FG-220P	FG-220P	874.4680 Bronchoscope (flexible or rigid) and accessories 874.4760 Nasopharyngoscope (flexible or rigid) and accessories	EOQ EOB
Single Use Grasping Forceps FG-226C	FG-226C	874.4680 Bronchoscope (flexible or rigid) and accessories	EOQ
Single Use	FG-232L	874.4680 Bronchoscope (flexible	EOQ

Grasping Forceps FG-232L		or rigid) and accessories	
Single Use Grasping Forceps FG-804L	FG-804L	874.4680 Bronchoscope (flexible or rigid) and accessories 874.4760 Nasopharyngoscope (flexible or rigid) and accessories	EOQ EOB

■ Common Name: Grasping Forceps

■ Regulatory Class: Class II

■ Classification Panel: Ear, Nose and Throat

3. PREDICATE DEVICE

■ **Predicate devices**

Device name	510(k) Submitter	510(k) No.
Olympus FG Series Reusable Grasping Forceps (FG-14P-1/FG-26C-1/FG-20P-1/FG-32L-1/FG-4L-1)	OLYMPUS MEDICAL SYSTEMS CORP.	K962533
Grasping Forceps FG-53SX-1	OLYMPUS MEDICAL SYSTEMS CORP.	K013591

4. DEVICE DESCRIPTION

■ **General Description of the subject device**
FG-214P, FG-226C, FG-232L, FG-804L
This instrument has been designed to be used with an Olympus endoscope to retrieve foreign bodies or resected tissue from the airways and tracheobronchial tree.

FG-214P and FG-804L have been also designed to be used with an Olympus endoscope to retrieve foreign bodies from the nasal lumens and airway anatomy (including nasopharynx and trachea).

The subject device is single-use grasping forceps sterilized by Ethylene Oxide.

The subject device consists of the Handle and the Insertion portion. The Insertion portion consists of the Distal end and the Sheath portion. The Handle consists of the Body and the Slider.

The subject device, after inserted into an endoscope from the Distal end, is used to grasp a foreign body or resected tissue with a pair of forceps (the Grasping jaws) at the Distal end by operating the Handle. The foreign body or the resected tissue is retrieved by removing the subject device together with the endoscope from the patient.

FG-220P

This instrument has been designed to be used with an Olympus endoscope to retrieve foreign bodies from the airways and tracheobronchial tree.

This instrument has also been designed to be used with an Olympus endoscope to retrieve foreign bodies from the nasal lumens and airway anatomy (including nasopharynx and trachea).

The subject device is single-use grasping forceps sterilized by Ethylene Oxide.

The subject device consists of a Handle and an Insertion portion. The Insertion portion consists of the Distal end and the Sheath portion. The Handle consists of the Body and the Slider.

The subject device, after inserted into an endoscope from the Distal end, is used to grasp a foreign body with a pair of forceps (the Grasping jaws) at the Distal end by operating the Handle. The foreign body is retrieved by removing the subject device together with the endoscope from the patient.

■ Principle of Operation

The subject device retrieves foreign bodies or resected tissue. The device interacts with the patient as follows.

The subject device is inserted into the biopsy valve of an endoscope while its grasping jaws closed by pulling the slider. It is advanced until the distal end of the insertion portion appears within the endoscopic field of view.

To grasp a foreign body or resected tissue, the slider is pushed to open the grasping jaws. Pull the slider to grasp the foreign body or the resected tissue.

The subject device is retrieved from the patient with the endoscope to remove the

foreign body or the resected tissue.

5. INDICATIONS FOR USE

Single Use Grasping Forceps FG-214P, FG-804L

This instrument has been designed to be used with an Olympus endoscope to retrieve foreign bodies or resected tissue from the nasal lumens and airway anatomy (including nasopharynx and trachea).

This instrument has been designed to be used with an Olympus endoscope to retrieve foreign bodies or resected tissue from the airways and tracheobronchial tree.

Single Use Grasping Forceps FG-226C, FG-232L

This instrument has been designed to be used with an Olympus endoscope to retrieve foreign bodies or resected tissue from the airways and tracheobronchial tree.

Single Use Grasping Forceps FG-220P

This instrument has been designed to be used with an Olympus endoscope to retrieve foreign bodies from the nasal lumens and airway anatomy (including nasopharynx and trachea).

This instrument has been designed to be used with an Olympus endoscope to retrieve foreign bodies from the airways and tracheobronchial tree.

6. COMPARISON OF TECHNOLOGY CHARACTERISTICS WITH THE PREDICATE DEVICES

The Single Use Grasping Forceps has the same technological characteristics and design as the predicate devices except for the following new features:

- ETO sterilized
- Single use
- Handle design
- Material

All other technological characteristics of both the subject and predicate devices are the same as the predicate devices.

Validation from non-clinical testing demonstrated that these technological features do not raise any new issues of safety or effectiveness compared to the predicate devices.

7 PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

1) Sterilization/Shelf life testing

Sterilization/shelf life testing were conducted in accordance with the FDA's Guidance for Industry and Food and Drug Administration Staff, "Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile".

Accelerated aging test was conducted in accordance with ASTM F1980-16, the standard guide for accelerated aging of sterile barrier systems for medical devices. The real-time aging test for three-years will be performed to demonstrate longer stability and support the results of the accelerated aging test.

2) Biocompatibility testing

Biocompatibility testing were 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 the following tests:

- Cytotoxicity Study Using the Colony Assay
- Intracutaneous Study in Rabbits
- Guinea Pig Maximization Sensitization Test

- Acute Systemic Toxicity Study in Mice

3) Performance testing - Bench

Bench testing as listed below were conducted to ensure that the subject device performs as intended and meet design specifications.

- Insertability into the endoscope
- Open and close of the grasping jaws
- Grasping performance
- Withdrawal property from the endoscope
- Device reliability
- Burr and/or edge of the insertion portion
- Strength of junction
- Breakage tolerance of the forceps

4) Risk management

Risk management was performed in accordance with ISO 14971:2007. The design verification tests and their acceptance criteria were identified and performed as a result of this risk management.

8. CONCLUSIONS

Based on the indications for use, technological characteristics, performance testing and technological comparison to the predicate devices, the Single Use Grasping Forceps do not raise different questions of safety and effectiveness and are substantially equivalent to the predicate devices in terms of safety, effectiveness and performance.