April 24, 2020

Olympus Medical Systems Corp.
% Jonathan Gilbert
Regulatory Affairs Consultant to OCA
Olympus Corporation of the Americas
3500 Corporation Parkway PO Box 610
Center Valley, Pennsylvania 18034-0610

Re: K200397
Trade/Device Name: Single Use Biopsy Forceps FB-456D
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: February 15, 2020
Received: February 18, 2020

Dear Jonathan Gilbert:

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 Michael J. Ryan
Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K200397

Device Name
Single Use Biopsy Forceps FB-456D

Indications for Use *(Describe)*
The biopsy forceps has been designed specifically to collect tissue endoscopically for examination in conjunction with a flexible Olympus bronchoscope.

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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K200397 510(k) Summary
Single Use Biopsy Forceps FB-456D

April 23, 2020

1. General Information

■ 510(k) submitter: OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho, Hachioji-shi, Tokyo, 192-8507, Japan
Establishment Registration No: 8010047

■ Contact Person: Jon Gilbert fbo Sheri L. Musgnung
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Center Valley, PA 18034-0610, USA
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■ Manufacturing site: Aomori Olympus Co., Ltd.
2-248-1 Okkonoki, Kuroishi-shi, Aomori, 036-0357, Japan
Establishment Registration No.: 9614691

2. Device Identification

■ Device Trade Name: Single Use Biopsy Forceps FB-456D

■ Common Name: Single Use Biopsy Forceps

■ Regulation Number: 874.4680

■ Regulation Name: Bronchoscope (flexible or rigid) and accessories

■ Regulatory Class: II

■ Classification Panel: Ear Nose & Throat

■ Product Code: EOQ

3. Predicate Device Information

Predicate device

■ Device Name: Single Use Biopsy Forceps FB-433D

■ Common Name: Biopsy Forceps

■ Applicant OLYMPUS MEDICAL SYSTEMS CORP.

■ 510(k) No. K172726

4. Device Description

The biopsy forceps has been designed specifically to collect tissue endoscopically for examination in conjunction with a flexible Olympus bronchoscope.

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

The subject device is inserted into the channel of a bronchoscope to collect tissue by biting the surface of lesions with the pair of cups affixed to the distal end of the subject device. Users withdraw the subject device from the bronchoscope channel to collect the biopsy sample.

The subject device consists of the Handle and the Insertion portion. The Handle consists of the Body and the Slider. The Insertion portion is divided into the Distal end including the Cups as well as other connection parts, and the Sheath portion including the Operation wire, the Coil sheath and other joint pipes. The Handle Slider is designed to connect to the Operation wire in the Insertion portion and the Cups, actuating the Cups to open/close by advancing and retracting the Slider.

5. Indications for Use

The biopsy forceps has been designed specifically to collect tissue endoscopically for examination in conjunction with a flexible Olympus bronchoscope.

6. Comparison of Technological Characteristics

In comparison to the predicate device, the subject device, Single Use Biopsy Forceps FB-456D, has similar technological characteristics except for the following differences.

- Cup shape
- Maximum insertion portion diameter
- Bronchoscope compatibility
- Configuration of handle
- Patient-contact material

The differences above have been validated and demonstrate that these technological features do not raise new issues in terms of the claims of substantial equivalence to the subject device.

7. Summary of non-clinical testing

The technological differences between the predicate device and the subject device have been verified and validated by means of the following tests and standards to endorse the claims of substantial equivalence to the predicate device.

Risk analysis was conducted in accordance with established in-house acceptance criteria based on ISO 14971:2007. The design verification tests and their acceptance criteria were identified and performed as a result of this risk analysis assessment.

Biocompatibility testing for Single Use Biopsy Forceps FB-456D 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".

Sterilization and shelf-life testing for the Single Use Biopsy Forceps FB-456D was 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". Sterilization validation was carried out with the method of Half-cycle approach in accordance with ISO 11135:2014. The shelf-life for three years has been validated by accelerated testing according to ASTM F1980-16. Three-year aging analyses will be performed to support the results of the accelerated aging test.

The requirements on packaging for terminally sterilized medical device per AAMI/ ANSI/ISO 11607-1/2 have also been validated. Performance testing as below was carried out to demonstrate the safety and the effectiveness of the subject device.

1. Compatibility with the endoscope
2. Open and close of the cups
3. Performance after repeated operation
4. Maximum insertion portion diameter
5. Visual inspection of the insertion portion
6. Strength of the junction and cups
7. Strength when opening/closing the cups
8. Package inspection

The following standards have been applied to the subject device.

Standard No.	Standard Title
ISO11135 Second Edition 2014	Sterilization of Health-Care Products, Ethylene Oxide - Requirements for the Development, Validation and Routine Control of a Sterilization Process for Medical Devices
ISO 10993-7 Second edition 2008-10-15	Biological evaluation of medical devices - part 7: ethylene oxide sterilization residuals
ISO 11607-1 First edition 2006-04-15	Packaging for terminally sterilized medical devices - part 1: requirements for materials, sterile barrier systems and packaging systems
ISO 11607-2 First edition 2006-04-15	Packaging for terminally sterilized medical devices - part 2: validation requirements for forming, sealing and assembly processes
ASTM F1980-16	Standard Guide For Accelerated Aging Of Sterile Barrier Systems For Medical Devices
ISO 10993-1 Fourth edition 2009-10-15	Biological evaluation of medical devices - part 1: evaluation and testing within a risk management process
ISO 10993-5 Third edition 2009-06-01	Biological evaluation of medical devices - part 5: tests for in vitro cytotoxicity
ISO 10993-10 Third Edition 2010-08-01	Biological evaluation of medical devices - part 10: tests for irritation and skin sensitization
ISO 10993-11 Third edition 2017-09	Biological evaluation of medical devices - part 11: tests for systemic toxicity
ISO 14971 Second edition 2007-03-01	Medical devices - application of risk management to medical devices

8. Conclusion

In comparison to the predicate device, the subject Single Use Biopsy Forceps FB-456D device does not raise different questions of safety and effectiveness and is substantially equivalent to the predicate device.