November 30, 2018

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

Re: K173495
Trade/Device Name: Single Use Hot Biopsy Forceps FD-231
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic Electrosurgical Unit and Accessories
Regulatory Class: Class II
Product Code: QEC
Dated: October 30, 2018
Received: October 31, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

James J. Lee -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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)*
K173495

Device Name
Single Use Hot Biopsy Forceps FD-231

Indications for Use *(Describe)*
This instrument has been designed to be used with an Olympus endoscope to electrosurgically collect tissue, to electrosurgically cauterize, or to perform electrosurgical hemostasis within the tracheobronchial tree.

The product is only intended for adult populations.

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
Single Use Hot Biopsy Forceps FD-231

November 29, 2018

5.1 General Information

■ Applicant:

OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho, Hachioji-shi, Tokyo, 192-8507, Japan
Establishment Registration No: 8010047

■ Official Correspondent:

Jon Gilbert fbo Sheri 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

■ Manufacturer:

Aomori Olympus Co., Ltd.
2-248-1 Okkonoki, Kuroishi-shi, Aomori, 036-0357, Japan
Establishment Registration No.: 9614691

5.2 Device Identification

■ Device Trade Name: Single Use Hot Biopsy Forceps FD-231

■ Model Number: FD-231C

■ Common Name: Hot Biopsy Forceps

■ Regulation Number: 876.4300

■ Regulation Name: Endoscopic electrosurgical unit and accessories.

■ Regulatory Class: II

■ Classification Panel: Gastroenterology/Urology

■ Product Code: QEC

5.3 Predicate Device and Reference Devices Information

	Predicate device	Reference device 1	Reference device 2
Device name	Disposable Hot Biopsy Forceps	Single Use Biopsy Forceps FB-433D	OLYMPUS CD-6C-1 COAGULATION ELECTRODE
K number	K160625	K172726	K971328
Classification	II	II	II

5.4 Device Description

Single Use Hot Biopsy Forceps FD-231 has been designed to be used with an Olympus endoscope to electrosurgically collect tissue, to electrosurgically cauterize, or to perform electrosurgical hemostasis within the tracheobronchial tree.

The Single Use Hot Biopsy Forceps FD-231consists of a handle and insertion portion. Fenestrated cups in the distal end of insertion portion are activated in the open and closed position by maneuvering the slider in the handle.

During operation, insertion portion will be inserted into endoscopes. Once the tissue is held by the cups, the tissue is subjected to high frequency electric current transmitted from plug which allows for collecting tissue. Once the tissue is touched by closed cups, the tissue is subjected to high frequency electric current transmitted from plug which allows for cauterization and hemostasis.

By means of high frequency electric current passing through the tissues between electrical plate attached on patient`s skin and the cups, heat will be produced from electricity resistance by the tissue and the heat will be utilized for collecting tissue, cauterization and hemostasis.

5.5 Indications for Use

This instrument has been designed to be used with an Olympus endoscope to electrosurgically collect tissue, to electrosurgically cauterize, or to perform electrosurgical hemostasis within the tracheobronchial tree.

The product is only intended for adult populations.

5.6 Comparison of Technological Characteristics

Compared to the predicate device, the proposed subject device: Single Use Hot Biopsy Forceps FD-231, has similar technological characteristics except for the following differences:

1. Compatible endoscope and accessories
2. Electrical specification for electrosurgical biopsy
3. Material composition and configuration of handle and insertion portion

Validation from non-clinical testing demonstrated that these technological features do not raise further problems on safety or effectiveness of the subject device.

5.7 Summary of non-clinical testing

The following tests on key features of performance specification were conducted to demonstrate the safety and effectiveness of the subject device as identical as predicate devices.

1. Insertion into /Withdrawal from endoscope of Hot Biopsy Forceps
2. Advance/ retraction of Hot Biopsy Forceps
3. Grasp of specimens
4. Electrical characteristic
5. Cutting performance test
6. Compatibility with endoscope
7. Visual inspection of package
8. Peel strength of the package
9. Endurance to splitting of the package
10. Integrity of the package
11. Joint strength test
12. Power limit

The EO residual and ECH residual were measured after sterilization of the device to meet the criteria defined in ISO 11135 Second edition 2014 and AAMI/ANSI/ISO 10993-7:2008(R)2012.

The shelf-life for three years had been validated in accelerated testing according to ASTM F1980-16 (2016) and the requirements on packaging for terminally sterilized medical device per AAMI/ANSI/ISO 11607-1:2006/(R) 2010 and AAMI/ANSI/ISO 11607-2:2006/(R)2010 are also met.

Biocompatibility testing was performed in accordance with the FDA Guidance, "Use of International Standard ISO-10993-1, 'Biological evaluation of medical devices - Part 1:

Evaluation and testing within a risk management process" issued on June 16, 2016. The cytotoxicity, sensitization, intracutaneous irritation and system toxicity tests were performed to demonstrate the biocompatibility of the device.

Tests on Electromagnetic Compatibility and Electrical Safety were performed in accordance to requirements per AAMI/ANSI ES 60601-1:2005/(R)2012 and A1:2012 and IEC 60601-1-2 Edition 3: 2007-03, and in particular we also conducted tests on high frequency surgical equipment and accessories for endoscopes per IEC 60601-2-18: Edition 3.0 2009-08 and AAMI/ANSI/IEC 60601-2-2:2009.

Risk analysis was carried out in accordance with established in-house acceptance criteria based on ISO 14971 Second edition 2007-03-01. The design verification tests and their acceptance criteria were identified and performed as a result of this risk analysis assessment.

The following standards have been applied to the Single Use Hot Biopsy Forceps FD-231:

Standard No.	Standard Title
AAMI/ANSI/ES 60601-1:2005/(R)2012 and A1:2012	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2 Edition 3: 2007-03	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
AAMI/ANSI/IEC 60601-2-2:2009	Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories
IEC 60601-2-18: Edition 3.0 2009-08	Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment
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

Standard No.	Standard Title
ISO 10993-10 Third Edition 2010-08-01	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
ISO 10993-11 Second edition 2006-08-15	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
ISO 11135 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
AAMI/ ANSI/ISO 10993-7 :2008(R)2012	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
ASTM F1980-16 (2016)	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
AAMI/ANSI/ISO 11607-1:2006/(R)2010	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
AAMI/ANSI/ISO 11607-2:2006/(R)2010	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
ISO 14971 Second edition 2007-03-01	Medical devices - Application of risk management to medical devices

5.8 Conclusion

Compared to the predicate device, the Single Use Hot Biopsy Forceps FD-231 does not demonstrate any significant changes in intended use and technical characteristics that could affect the safety or effectiveness of the device.