April 30, 2018

Olympus Medical Systems Corp.
% Daphney Germain-Kolawole
Senior Project Manager, Regulatory Affairs
Olympus Corporation of the Americas
3500 Corporate Parkway
PO Box 610
Center Valley, PA 18034-0610

Re: K172726
Trade/Device Name: EVIS EXERA III BRONCHOFIBERVIDEOSCOPE OLYMPUS BF-MP190F, Single Use Biopsy Forceps FB-433D
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: March 29, 2018
Received: March 30, 2018

Dear Daphney Germain-Kolawole:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 yours,

Eric A. Mann -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat 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)*
K172726

Device Name
EVIS EXERA III BRONCHOFIBERVIDEOSCOPE OLYMPUS BF-MP190F
Single Use Biopsy Forceps FB-433D

Indications for Use *(Describe)*

- EVIS EXERA III BRONCHOFIBERVIDEOSCOPE OLYMPUS BF-MP190F
This instrument is intended to be used with an Olympus video system center, light source, documentation equipment, monitor, EndoTherapy accessories (such as a biopsy forceps), and other ancillary equipment for endoscopy and endoscopic surgery. This instrument is indicated for use within the airways and tracheobronchial tree.

- Single Use Biopsy Forceps FB-433D
The biopsy forceps has been designed specifically to collect tissue endoscopically for examination in conjunction with a flexible 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.

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510(k) SUMMARY
BRONCHOFIBERVIDEOSCOPE BF-MP190F
Single Use Biopsy Forceps FB-433D

April 27, 2018

1. General Information

■ Applicant:

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

■ Official Correspondent:

Daphney Germain-Kolawole
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Center Valley, PA 18034-0610, USA
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■ Manufacturer:

AIZU OLYMPUS CO., LTD.
500 Muranishi, Niidera Monden-Machi
Aizuwakamatsu-shi Fukushima, JAPAN 965-8520
Establishment Registration No.: 9610595

Aomori Olympus Co., Ltd.
248-1 Okkonoki 2-chome Kuroishi-shi,
Aomori, Japan 036-0357
Establishment Registration No.: 9614641

2. Device Identification

■ Device Trade Name and Model number (if applicable):

·EVIS EXERA III BRONCHOFIBERVIDEOSCOPE OLYMPUS BF-MP190F
·Single Use Biopsy Forceps FB-433D

■ Common Name:

·Bronchoscope, its accessories and ancillary equipment
·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; Bronchoscope (Flexible Or Rigid)
EOB; Nasopharyngoscope (Flexible Or Rigid)

3. Predicate Device/ Reference devices Information

[EVIS EXERA III BRONCHOFIBERVIDEOSCOPE OLYMPUS BF-MP190F]
Predicate device

Device Trade Name	Common Name	Applicant	510(k) No.
OLYMPUS BF-Q190 EVIS EXERA Ⅲ BRONCHOVIDEOSCOPE	Bronchoscope, its accessories and ancillary equipment	OLYMPUS MEDICAL SYSTEMS CORP.	K121959

Reference device

Device Trade Name	Common Name	Applicant	510(k) No.
EVIS EXERA BRONCHOFIBERVIDEOSCOPE OLYMPUS BF TYPE XP160F	Bronchoscope, its accessories and ancillary equipment	OLYMPUS OPTICAL CO., LTD.	K033225

[Single Use Biopsy Forceps FB-433D]

Device Trade Name	Common Name	Applicant	510(k) No.
DISPOSABLE BIOPSY FORCEPS FB-49C	OLYMPUS DISPOSABLE BIOPSY FORCEPS	Olympus America Inc.	K950636

The predicate devices have not been subject to a design-related recall.

4. Device Description

[EVIS EXERA III BRONCHOFIBERVIDEOSCOPE OLYMPUS BF-MP190F]

The BF-MP190F is intended to be used with an Olympus video system center, light source, documentation equipment, monitor, EndoTherapy accessories (such as a biopsy forceps), and other ancillary equipment for endoscopy and endoscopic surgery.

The BF-MP190F is indicated for use within the airways and tracheobronchial tree.

The BF-MP190F is a flexible video endoscope used for endoscopic diagnosis and treatment within the respiratory organs and a modification of the BF-Q190 which was previously cleared under K121959. The BF-MP190F has been designed to be applicable for diagnosis and treatment in the peripheral portion of the tracheobronchial trees compared to the predicate model.

The basic principle, the user interface and operation for the bronchoscopic procedure of the BF-MP190F is identical to the predicate BF-Q190.

[Single Use Biopsy Forceps FB-433D]

The biopsy forceps has been designed specifically to collect tissue endoscopically for examination in conjunction with a flexible bronchoscope. Identical to the predicate device, the subject device is inserted into the channel of an endoscope to collect tissue with the pair of forceps which is equipped at the distal end of the subject device. Then users withdraw the subject device from the channel and collect samples.

5. Indications for Use

[EVIS EXERA III BRONCHOFIBERVIDEOSCOPE OLYMPUS BF-MP190F]

This instrument is intended to be used with an Olympus video system center, light source, documentation equipment, monitor, EndoTherapy accessories (such as a biopsy forceps), and other ancillary equipment for endoscopy and endoscopic surgery. This instrument is indicated for use within the airways and tracheobronchial tree.

[Single Use Biopsy Forceps FB-433D]

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

6. Comparison of Technological Characteristics

[EVIS EXERA III BRONCHOFIBERVIDEOSCOPE OLYMPUS BF-MP190F]

Compared to the proposed predicate device, the subject device, EVIS EXERA III BRONCHOFIBERVIDEOSCOPE OLYMPUS BF-MP190F, incorporated the following modifications:

- Function of narrow band imaging is unavailable
- Position of the CCD unit is changed from distal end to control section
- Outer diameter of the insertion portion is shorter
- Instrument channel size is narrower
- Material of distal end and light guide lens in insertion portion has been altered

- The optical properties are changed to accommodate to the narrowed insertion portion
- Additional sterilization methods for reprocessing

Validation from non-clinical testing demonstrated that these technological features do not raise any new issues of safety or effectiveness of the subject device.

A side-by-side comparison of the subject device and the predicate device is provided below.

Item	<Subject Device> BF-MP190F #K172726	<Predicate Device> BF-Q190 # K121959
Indications for use	This instrument is intended to be used with an Olympus video system center, light source, documentation equipment, monitor, EndoTherapy accessories (such as a biopsy forceps), and other ancillary equipment for endoscopy and endoscopic surgery. This instrument is indicated for use within the airways and tracheobronchial tree.	This instrument is intended to be used with an Olympus video system center, light source, documentation equipment, monitor, EndoTherapy accessories (such as a biopsy forceps), and other ancillary equipment for endoscopy and endoscopic surgery. This instrument is indicated for use within the airways and tracheobronchial tree.
Common name	BRONCHOSCOPE	BRONCHOSCOPE
Regulation number	874.4680	874.4680
Regulation name	Bronchoscope (flexible or rigid) and accessories	Bronchoscope (flexible or rigid) and accessories
Regulatory class	II	II
Classification panel	Ear Nose & Throat	Ear Nose & Throat
Product code	EOQ,EOB	EOQ,EOB,NWB
Environment of use	Healthcare facility/hospital	Healthcare facility/hospital
Single/repeat use	Repeat use	Repeat use
Sterile/non-sterile	Marketed as non-sterile	Marketed as non-sterile
Sterilization method	Ethylene oxide; Hydrogen peroxide	Ethylene oxide; Hydrogen peroxide
Energy source	Electricity	Electricity
Field of View	90˚	120˚
Depth of Field	2-50mm	3-100mm
Direction of View	0°(Forward viewing)	0°(Forward viewing)
Image sensor	CCD (in the control section)	CCD (in the distal end)
NBI observation	Not available	Available

Item	<Subject Device> BF-MP190F #K172726	<Predicate Device> BF-Q190 # K121959
Angulation UP/DOWN	UP:210°, DOWN:130°	UP:210°, DOWN:130°
Working Length	600mm	600mm
Inner Diameter of Instrument Channel	φ1.7mm	φ2.0mm
Outer Diameter of Distal End	φ3.0mm	φ4.8mm
Outer Diameter of Insertion Tube	φ3.7mm	φ6.0mm
High frequency accessories	Not compatible	Compatible
Material composition of main patient-contact parts and duration and type of contact	Material composition of main patient-contact parts Distal tip: Stainless steel Insertion tube: Resin Bending rubber: Rubber Lens: Glass Adhesive: Epoxy Surface-contacting device in contact with mucosal membranes. The contact duration is limited exposure (i.e. contact is up to 24 hours).	Material composition of main patient-contact parts Distal tip: Polymer Insertion tube: Resin Bending rubber: Rubber Lens: Polymer Adhesive: Epoxy Surface-contacting device in contact with mucosal membranes. The contact duration is limited exposure (i.e. contact is up to 24 hours).

[Single Use Biopsy Forceps FB-433D]
Compared to the predicate device, the proposed subject device, Single Use Biopsy Forceps FB-433D, mainly has the following technical differences:

-Compatible devices
-Maximum diameter and length of insertion portion
-Cup and its rigid portion size and material.

Validation from non-clinical testing demonstrated that these technological features do not raise any new issues of safety or effectiveness of the subject device.

A side by side comparison of the subject device and the predicate device is provided below.

Item	<Subject Device> Single Use Biopsy Forceps FB-433D #K172726	<Predicate Device> FB-49C #K950636
Indications for use	The biopsy forceps has been designed specifically to collect tissue endoscopically for examination in conjunction with a flexible bronchoscope.	The Olympus Disposable Biopsy Forceps are specifically designed to collect tissue endoscopically for examination in conjunction with flexible bronchoscopes and rhino-laryngoscopes.
Common name	OLYMPUS DISPOSABLE BIOPSY FORCEPS	N/A
Regulation number	874.4680	874.4680
Regulation name	Bronchoscope (flexible or rigid) and accessories	Bronchoscope (flexible or rigid) and accessories
Regulatory class	II	II
Classification panel	Ear Nose & Throat	Ear Nose & Throat
Product code	EOQ	EOQ
Environment of use	Healthcare facility/hospital	Healthcare facility/hospital
Single/repeat use	Single use	Single use
Sterile/non-sterile	Sterile	Sterile
Sterilization method	Ethylene oxide	Ethylene oxide
Energy source	Mechanical	Mechanical
Maximum insertion portion diameter	φ1.5 mm	φ1.8 mm
Working length	1150 mm	1050 mm
Cup shape and size	Oval shaped portion Maximum diameter: ϕ 1.5 mm	Oval shaped portion Maximum diameter: ϕ 1.8mm
Sheath type	Metal coil	Metal coil
Material composition of main patient-contact parts and duration and type of contact	Material composition of main patient-contact parts Cups: Stainless metal Coil sheath: Stainless metal Surface-contacting device in contact with mucosal membranes. The contact duration is limited exposure (i.e. contact is up to 24 hours).	Material composition of main patient-contact parts Cups: Stainless metal Coil sheath: Stainless metal Surface-contacting device in contact with mucosal membranes. The contact duration is limited exposure (i.e. contact is up to 24 hours).

7. Summary of non-clinical testing

The technological characteristic differences between the predicate devices and the subject devices have been confirmed that they are substantially equivalent through the following tests and standards.

•Risk analysis was carried out 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.
(For BRONCHOFIBERVIDEOSCOPE BF-MP190F and Single Use Biopsy Forceps FB-433D)

•Biocompatibility testing was performed in accordance with the FDA Guidance, Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a risk management process` issued on June 16 2016. (For BRONCHOFIBERVIDEOSCOPE BF-MP190F and Single Use Biopsy Forceps FB-433D)

•Performance testing was carried out to demonstrate the safety and the effectiveness of the subject device.

[EVIS EXERA III BRONCHOFIBERVIDEOSCOPE OLYMPUS BF-MP190F]
- Thermal safety test
- Mechanical durability test

[Single Use Biopsy Forceps FB-433D]
- Forceps operation with the compatible endoscope
- Dimension of each part of the forceps
- General durability
- Integrity of the package

•The software validation activities were performed in accordance with the FDA Guidance, “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices” issued on May 11, 2005.
(For EVIS EXERA III BRONCHOFIBERVIDEOSCOPE OLYMPUS BF-MP190F)

•Electromagnetic compatibility, electric safety, and thermal safety had been confirmed. (For EVIS EXERA III BRONCHOFIBERVIDEOSCOPE OLYMPUS BF-MP190F)

•The reprocessing validation test (cleaning, manual and automated high-level disinfection and sterilization) was performed in accordance with the FDA guidance “Guidance for Industry and FDA Staff - Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling issued on March 17, 2015”
(For EVIS EXERA III BRONCHOFIBERVIDEOSCOPE OLYMPUS BF-MP190F)

•Sterilization validation
Sterilization validation was carried out with Method Half-cycle approach in accordance with ISO 11135:2014. (For Single Use Biopsy Forceps FB-433D)

•Shelf-life testing was conducted based on an accelerated aging test in accordance with ASTM F1980-16, the standard guide for accelerated aging of sterile barrier systems for medical devices. Three-year aging test will be performed to demonstrate longer stability and support the results of the accelerated aging test. The requirements on packaging for terminally sterilized medical device per AAMI/ANSI/ISO 11607-1/2 had also been met. (For the Single Use Biopsy Forceps FB-433D)

The following standards have been applied to the subject devices.

Standard No.	Standard Title	Subject devices
ISO 14971 Second Edition: 2007-03-01	Medical Devices - Application Of Risk Management To Medical Devices	· EVIS EXERA III BRONCHOFIBERVIDEOSCOPE OLYMPUS BF-MP190F ·Single Use Biopsy Forceps FB-433D
ISO 10993-1 Fourth Edition:2009-10-15	Biological Evaluation Of Medical Devices - Part1: Evaluation And Testing Within A Risk Management Process [Including: Technical Corrigendum 1 (2010)]	· EVIS EXERA III BRONCHOFIBERVIDEOSCOPE OLYMPUS BF-MP190F ·Single Use Biopsy Forceps FB-433D
AAMI ANSI ISO 10993-5:2009/(R)2014	Biological Evaluation Of Medical Devices – Part5: Tests For In Vitro Cytotoxicity	· EVIS EXERA III BRONCHOFIBERVIDEOSCOPE OLYMPUS BF-MP190F ·Single Use Biopsy Forceps FB-433D
ISO 10993-10 Third Edition: 2010-08-01	Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization	· EVIS EXERA III BRONCHOFIBERVIDEOSCOPE OLYMPUS BF-MP190F ·Single Use Biopsy Forceps FB-433D
ISO 10993-11 Second Edition 2006-08-15	Biological Evaluation Of Medical Devices, Part 11: Tests For Systemic Toxicity	·Single Use Biopsy Forceps FB-433D
AAMI ANSI ES60601-1:2005/(R)2012 and A1:2012	Medical Electrical Equipment – Part 1: General Requirements for Basic Safety And Essential Performance + Amendment 1: 2012	· EVIS EXERA III BRONCHOFIBERVIDEOSCOPE OLYMPUS BF-MP190F
IEC 60601-1-2 Edition 4.0: 2014-02	Medical Electrical Equipment – Part 1-2: General Requirements for Safety – Collateral standard: Electromagnetic Compatibility –	· EVIS EXERA III BRONCHOFIBERVIDEOSCOPE OLYMPUS BF-MP190F

Standard No.	Standard Title	Subject devices
	Requirements and Tests	
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.	· EVIS EXERA III BRONCHOFIBERVIDEOSCOPE OLYMPUS BF-MP190F
ASTM E1837-96 (Reapproved 2014)	Standard Test Method to Determine Efficacy of Disinfection Processes for Reusable Medical Devices (Simulated Use Test)	· EVIS EXERA III BRONCHOFIBERVIDEOSCOPE OLYMPUS BF-MP190F
ISO 10993-7 Second edition 2008-10-15	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals [Including: Technical Corrigendum 1 (2009)]	EVIS EXERA III BRONCHOFIBERVIDEOSCOPE OLYMPUS BF-MP190F ·Single Use Biopsy Forceps FB-433D
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.	· EVIS EXERA III BRONCHOFIBERVIDEOSCOPE OLYMPUS BF-MP190F ·Single Use Biopsy Forceps FB-433D
ASTM F1980-16	Standard Guide For Accelerated Aging Of Sterile Barrier Systems For Medical Devices	·Single Use Biopsy Forceps FB-433D
AAMI/ANSI/ISO 11607-1	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems [Including: Amendment 1 (2014)]	·Single Use Biopsy Forceps FB-433D
AAMI/ANSI/ISO 11607-2	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes [Including: Amendment 1 (2014)]	·Single Use Biopsy Forceps FB-433D

8. Conclusion

The EVIS EXERA III BRONCHOFIBERVIDEOSCOPE OLYMPUS BF-MP190F

and Single Use Biopsy Forceps FB-433D are substantially equivalent to their proposed predicate devices, respectively.