September 5, 2019

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: K183419
Trade/Device Name: EVIS EXERA III Bronchovideoscope Olympus BF-XT190
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: August 1, 2019
Received: August 2, 2019

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 Srinivas Nandkumar, Ph.D.
Assistant 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)*
K183419

Device Name
EVIS EXERA III BRONCHOVIDEOSCOPE OLYMPUS BF-XT190

Indications for Use *(Describe)*
- EVIS EXERA III BRONCHOVIDEOSCOPE OLYMPUS BF-XT190
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.

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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September 3, 2019

510(k) Summary

5.1 GENERAL INFORMATION

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

■ 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

5.2 DEVICE IDENTIFICATION

■ Device Name: EVIS EXERA III BRONCHOVIDEOSCOPE OLYMPUS BF-XT190
■ Model Name: OLYMPUS BF-XT190
■ Common Name: Bronchoscope, its accessories and ancillary equipment
■ Regulation Number: 874.4680
■ Regulation Name: Bronchoscope (flexible or rigid) and accessories
■ Regulatory Class: II
■ Product Code: EOQ, Bronchoscope (Flexible Or Rigid)
■ Classification Panel: Ear, Nose, and Throat

5.3 PREDICATE DEVICE

■ **Predicate device**

Device name	510(k) Submitter	510(k) No.
OLYMPUS BF-MP190F	OLYMPUS MEDICAL SYSTEMS CORP.	K172726

5.4 DEVICE DESCRIPTION

■ **General Description of the subject device**

This EVIS EXERA III BRONCHOVIDEOSCOPE OLYMPUS BF-XT190 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-XT190 is indicated for use within the airways and tracheobronchial tree. The BF-XT190 is a video scope used for the endoscopic diagnosis and treatment within the respiratory organs and modification of the BF-MP190F which was previously cleared under K172726.

■ **Principle of Operation**

The BF-XT190 consists of three parts: the control section, the insertion section, and the connector section. The basic principal, the user interface and operation for the bronchoscopic procedure of the BF-XT190 is identical to the predicate BF-MP190F.

5.5 INDICATIONS FOR USE

- EVIS EXERA III BRONCHOVIDEOSCOPE OLYMPUS BF-XT190

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.

5.6 COMPARISON OF TECHNOLOGY CHARACTERISTICS WITH THE PREDICATE DEIVCE

The EVIS EXERA III BRONCHOVIDEOSCOPE OLYMPUS BF-XT190 has the same technological characteristics and design as the predicate device except for the following new features:

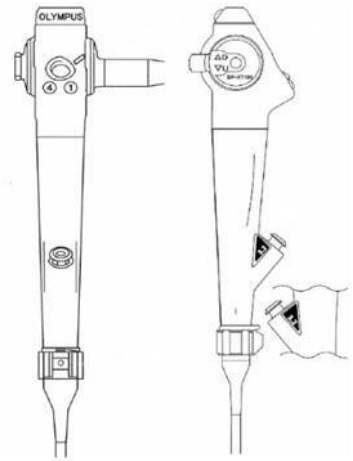
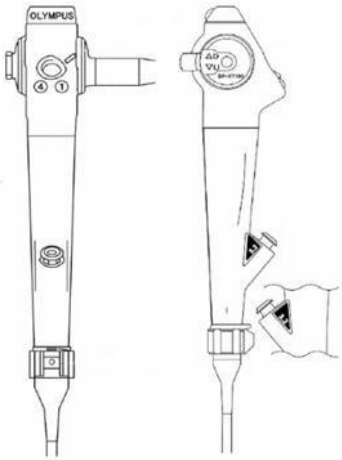
- Instrument channel is wider
- Insertion tube is wider
- Optical specification has been altered
- Bending section angulation is narrower
- Function of narrow band imaging (NBI) observation is available
- Patient contact materials have been altered

All other technological characteristics of both the subject and predicate device are identical.

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 EVIS EXERA III BRONCHOVIDEOSCOPE OLYMPUS BF-XT190	Predicate Device EVIS EXERA III BRONCHOFIBERVIDEOSCOPE OLYMPUS BF-MP190F (K172726)
Indications for use	This instrument is intended to be used with an Olympus video system center, light source, documentation	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.	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.
Depth of Field	2 – 50 mm	2 - 50 mm
Direction of Forward View	0° (Forward viewing)	0° (Forward viewing)
Field of View	110°	90°
NBI observation	Available	Not Available
Outer Diameter of Distal End	Φ6.1mm	φ3.0mm
Outer Diameter of Insertion Tube	Φ6.3mm	φ3.7mm
Bending Section Angulation	UP:180°, DOWN:130°	UP:210°, DOWN:130°
Working Length	600mm	600mm
Instrument Channel inner diameter [mm]	φ3.2	φ1.7
Configuration of Control section and location of scope switch		

5.7 PERFORMANCE DATA

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

1) Reprocessing validation testing

Reprocessing instruction and reprocessing method validation testing for the EVIS EXERA III BRONCHOVIDEOSCOPE OLYMPUS BF-XT190 were performed in accordance with the FDA guidance "Guidance for Industry and Food and Drug Administration Staff, - Reprocessing Medical Devices in Health Care Setting: Validation Methods and Labeling issued on March 17, 2015".

2) Biocompatibility testing

Biocompatibility testing for the EVIS EXERA III BRONCHOVIDEOSCOPE OLYMPUS BF-XT190 were 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, 2013". The biocompatibility testing includes the following tests:

- Cytotoxicity Study Using the Colony Assay – ISO-10993-5
- Intracutaneous Study in Rabbits – ISO-10993-10
- Guinea Pig Maximization Sensitization Test – ISO-10993-10
- Acute Systemic toxicity – ISO 10993-11

3) Software verification and validation testing

Software verification and validation testing for the EVIS EXERA III BRONCHOVIDEOSCOPE OLYMPUS BF-XT190 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" and "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, issued on October 2, 2014".

4) Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were performed on the EVIS EXERA III BRONCHOVIDEOSCOPE OLYMPUS BF-XT190. The system complies with the ANSI/AAMI ES 60601-1:2005/(R)2012 and A1:2012 and IEC 60601-2-18:2009 standards for safety and the IEC 60601-1-2:2014 standards for EMC.

5) Performance testing - Bench

Bench testing for the EVIS EXERA III BRONCHOVIDEOSCOPE OLYMPUS BF-XT190 was carried out to demonstrate the safety and the effectiveness of the subject device.

- Thermal Safety Test

- Mechanical Durability Test
- Photobiological Safety Test
- Optical Performance Test

6) Performance testing - Animal

No animal study was performed to demonstrate substantial equivalence.

7) Performance testing - Clinical

No clinical study was performed to demonstrate substantial equivalence.

8) Risk analysis

Risk analysis for the EVIS EXERA III BRONCHOVIDEOSCOPE OLYMPUS BF-XT190 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.

5.8 CONCLUSIONS

Based on the indications for use, technological characteristics, performance testing and technological comparison to the predicate device, the EVIS EXERA III BRONCHO VIDEOSCOPE OLYMPUS BF-XT190 raised no new issue of safety and effectiveness and are substantially equivalent to the predicate device in terms of safety, efficacy and performance.