January 21, 2021

Olympus Medical Systems Corp.
% Anne-Marie Keefe
Program Manager
Olympus Surgical Technologies of America
118 Turnpike Road, Suite 120
Southborough, Massachusetts 01772

Re: K201758
Trade/Device Name: EVIS EXERA III Bronchovideoscope Olympus BF-XP190, EVIS EXERA III Bronchovideoscope Olympus BF-P190
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (flexible or rigid) and accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: December 18, 2020
Received: December 21, 2020

Dear Anne-Marie Keefe:

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)*
K201758

Device Name
EVIS EXERA III BRONCHOVIDEOSCOPE OLYMPUS BF-XP190
EVIS EXERA III BRONCHOVIDEOSCOPE OLYMPUS BF-P190

Indications for Use *(Describe)*

EVIS EXERA III BRONCHOVIDEOSCOPE OLYMPUS BF-XP190
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.

EVIS EXERA III BRONCHOVIDEOSCOPE OLYMPUS BF-P190
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.

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."

Date prepared: January 21, 2021

K201758

510(k) Summary

1. GENERAL INFORMATION

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

■ Contact Person: Anne-Marie Keefe
Olympus Surgical Technologies of America
118 Turnpike Road, Suite 120
Southborough, MA 01772
Phone: (508) 804-2448
Fax: 484-896-7128
Mobile: (508) 244-1921
Email: Anne-Marie.Keefe@olymus.com

■ Manufacturing site: Aizu Olympus Co., Ltd.,
500 Muranishi, Niidera, Monden-machi, Aizuwakamatsu-shi,
Fukushima 965-8520, Japan

2. DEVICE IDENTIFICATION

■ Device Name: EVIS EXERA III BRONCHOVIDEOSCOPE OLYMPUS BF-XP190
EVIS EXERA III BRONCHOVIDEOSCOPE OLYMPUS BF-P190

■ Common Name: BRONCHOVIDEOSCOPE

■ Regulation Number: 874.4680

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

■ Regulatory Class: Class II

■ Product Code: EOQ (Bronchoscope (Flexible or rigid))

■ Classification Panel: Ear, Nose and Throat

3. PREDICATE DEVICE

■ **Predicate device**

Device name	510(k) Submitter	510(k) No.
OLYMPUS BF-XT190 EVIS EXERA III BRONCHOVIDEOSCOPE	OLYMPUS MEDICAL SYSTEMS CORP.	K183419

4. DEVICE DESCRIPTION

■ **General Description of the subject device**

This EVIS EXERA III BRONCHOVIDEOSCOPE (OLYMPUS BF-XP190, OLYMPUS BF-P190) 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 bronchovideoscope (BF-XP190, BF-P190) is indicated for use within the airways and tracheobronchial tree.

The bronchovideoscope (BF-XP190, BF-P190) is a video scope used for endoscopic diagnosis and treatment within the respiratory organs and modification of the BF-XT190 which was previously cleared under K183419.

■ **Principle of Operation**

The endoscope consists of three parts: the control section, the insertion section, and the connector section. The basic principle including user interface and operation for the procedure of the endoscope is identical to that of the predicate device, BF-XT190.

5. INDICATIONS FOR USE

■ EVIS EXERA III BRONCHOVIDEOSCOPE OLYMPUS BF-XP190

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.

- EVIS EXERA III BRONCHOVIDEOSCOPE OLYMPUS BF-P190
  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.

6. COMPARISON OF TECHNOLOGY CHARACTERISTICS WITH THE PREDICATE DEIVCE

The EVIS EXERA III BRONCHOVIDEOSCOPE OLYMPUS BF-XP190 has the same technological characteristics and design as the predicate device except for the following new features:

- 1.2 mm Inner Diameter of Instrument Channel
- 3.1 mm Outer Diameter of Distal End
- 2.8 mm Outer Diameter of Insertion Tube

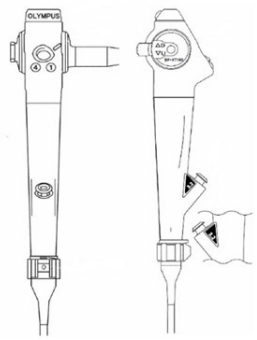
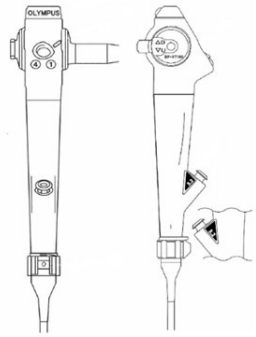
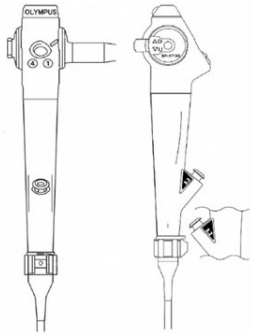
The EVIS EXERA III BRONCHOVIDEOSCOPE OLYMPUS BF-P190 has the same technological characteristics and design as the predicate device except for the following new features:

- 2.0 mm Inner Diameter of Instrument Channel
- 4.2 mm Outer Diameter of Distal End
- 4.1 mm Outer Diameter of Insertion Tube

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 BF-XP190	Subject Device BF-P190	Predicate Device BF-XT190 (K183419)
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.	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.
Depth of Field	2 - 50 mm	2 - 50 mm	2 - 50 mm
Direction of Forward View	0° (Forward viewing)	0° (Forward viewing)	0° (Forward viewing)
Field of View	110°	110°	110°
NBI observation	Available	Available	Available
Outer Diameter of Distal End	Φ3.1mm	Φ4.2mm	Φ6.1mm
Outer Diameter of	Φ2.8mm	Φ4.1mm	Φ6.3mm

Insertion Tube			
Bending Section Angulation	UP:210°, DOWN:130°	UP:210°, DOWN:130°	UP:180°, DOWN:130°
Working Length	600mm	600mm	600mm
Instrument Channel inner diameter	Φ1.2mm	Φ2.0mm	Φ3.2mm
Configuration of Control section and location of scope switch			

7 PERFORMANCE DATA

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

1) Reprocessing validation testing

Reprocessing instruction and reprocessing method validation testing was conducted and documentations were provided as recommended by 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 was 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 issued on June 16, 2016". The biocompatibility testing included 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)
- Systemic Toxicity Study in Mice (ISO 10993-11)

3) Software verification and validation testing

Software verification and validation testing was conducted and documentation is provided as recommended by FDA's Guidance for Industry and FDA Staff, "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 was conducted in accordance with ANSI/AAMI ES 60601-1:2005/(R)2012 and A1:2012 and IEC 60601-2-18:2009 standards for electrical safety and the IEC 60601-1-2:2014 standards for EMC.

5) Performance testing - Bench

Bench testing as listed below was conducted to ensure that the subject devices were carried out to demonstrate their safety and effectiveness.

- Thermal Safety Test
- Mechanical durability test
- Photobiological Safety 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 management

Risk management was performed in accordance with ISO 14971: 2007 (Second edition) and the human factors validation was conducted in accordance with the FDA Guidance, "Applying Human Factors and Usability Engineering to Medical Devices issued on February 3, 2016". 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 device, the EVIS EXERA III BRONCHOVIDEOSCOPE OLYMPUS BF-XP190 and BF-P190 raise no new issue of safety and effectiveness and are substantially equivalent to the predicate device in terms of safety, effectiveness, and performance.