September 6, 2019

Olympus Medical Systems Corp.
% Sheri Musgnung
Manager, Regulatory Affairs
Olympus Corporation of the Americas
3500 Corporate Parkway PO Box 610
Center Valley, Pennsylvania 18034-0610

Re: K183525
Trade/Device Name: EVIS EUS Ultrasound Bronchofibervideoscope Olympus BF-UC190F
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: PSV, ITX
Dated: August 8, 2019
Received: August 9, 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)*
K183525

Device Name

EVIS EUS ULTRASOUND BRONCHOFIBERVIDEOSCOPE OLYMPUS BF-UC190F

Indications for Use *(Describe)*

This instrument has been designed to be used with diagnostic ultrasound system, video system center, light source, documentation equipment, display monitor, EndoTherapy accessories such as an aspiration biopsy needle.
This instrument is designed for endoscopic real-time ultrasound imaging, for performing endoscopic ultrasound guided needle aspiration within the airways, tracheobronchial tree, and esophagus.

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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September 3, 2019

510(k) Summary

1 GENERAL INFORMATION

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

■ Contact Person: Sheri Musgnung
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2 DEVICE IDENTIFICATION

■ Device Name: EVIS EUS ULTRASOUND BRONCHOFIBERVIDEOSCOPE OLYMPUS BF-UC190F

■ Common Name: Ultrasound Bronchoscope

■ Regulation Number: 892.1550

■ Regulation Name: Ultrasonic pulsed doppler imaging system.

■ Regulatory Class: II

■ Product Code: PSV, ITX

■ Classification Panel: Ear, Nose, and Throat

3 PREDICATE DEVICE

Table 1.1.5-1 Predicate device on BF-UC190F

Device name	510(k) Submitter	510(k) No.
XBF-UC180F-DT8 (AKA BF-UC180F)	OLYMPUS MEDICAL SYSTEMS CORP.	K070983

The predicate device, XBF-UC180F-DT8, has been name changed after 510(k) clearance. It is marketed as BF-UC180F.

4 DEVICE DESCRIPTIONN

EVIS EUS BRONCHOVIDEOFIBERSCOPE OLYMPUS BF-UC190F

1) General Description of the subject device

The BF-UC190F has been designed to be used with the video system center, light source, documentation equipment, display monitor, and Endo Therapy accessories such as an aspiration biopsy needle. The BF-UC190F is intended for endoscopic real-time ultrasound imaging for performing endoscopic ultrasound guided needle aspiration within the airways, tracheobronchial tree, and esophagus.

The BF-UC190F is a flexible video endoscope and a modification of the XBF-UC180F-DT8 which was previously cleared under K070983.

2) Principle of Operation

The BF-UC190F consists of three parts: the control section, the insertion section, and the connector section.

The control section

The UP/DOWN angulation control lever on the control section is connected to the tip of the bending section by a series of wires. By operating the UP/DOWN angulation control lever, the bending section at the distal end bends vertically to guide the distal end for insertion and observation within the airways, tracheobronchial tree, and esophagus.

The endoscope contains a cylinder to attach a suction valve for suction. Depressing the suction valve will allow the doctor to use the endoscope to suction any fluids which are obscuring a good view of the tissue. Therapeutic instruments can be passed through the instrument channel for performing endoscopic biopsy and other therapies.

The insertion section

The insertion section has main parts including the image guide the light guide, the instrument channel, the balloon channel and the ultrasound transducer.

The light guides bring light from the light source through the endoscope.

The instrument channel outlet (also the suction opening) can be pushed in and out for withdrawing and inserting the therapeutic tools.

The balloon channel feed water to the balloon.

The ultrasound transducer emits and receives the ultrasound wave.

The connector section

The connector section connects the endoscope with the light source (CLV-190).

This connector contains the ultrasound cable connector to attach the ultrasound cable for connecting the ultrasound system.

The BF-UC190F is equipped with the CCD unit in the control section, as well as the fiber bundle in the insertion tube. Images are transmitted through the fiber bundle, and the CCD unit in the control section changes them to video signals. This feature is identical to the predicate models (XBF-UC180F-DT8; K070983).

Ultrasound Operation

Operating controls with ultrasound systems
The primary interface between the device and the user is the console's keyboard. The software controlling the keyboard has been designed as the user cannot set the machine to over-ride any of the internally set controls (such as maximum acoustic power).
In any mode, the keyboard menu will only accept valid inputs. Keys and/or commands are not available in a particular mode.
A trackball or a trackpad are provided for calipers, other graphic and imaging adjustments/ controls.

US CONNECTOR CAP MAJ-2295
This is US connector cap. This is attached to the ultrasound cable connector on the endoscope to protect the ultrasound cable connector and the endoscope from water penetration during reprocessing.

5 INDICATIONS FOR USE

This instrument has been designed to be used with diagnostic ultrasound system, video system center, light source, documentation equipment, display monitor, Endo Therapy accessories such as an aspiration biopsy needle.

This instrument is designed for endoscopic real-time ultrasound imaging, for performing endoscopic ultrasound guided needle aspiration within the airways, tracheobronchial tree, and esophagus.

6 COMPARISON OF TECHNOLOGY CHARACTERISTICS WITH THE PREDICATE DEIVCE

The BF-UC190F has the same technological characteristics and design as the predicate device except for the following new features:

a. Outer diameter of the insertion portion
b. Outer Diameter of Distal End
c. Direction of view.
d. Angulations
e. Electrical connector (transmit CCD image signal)

f. More sterilization methods become applicable for endoscope.
g. Irrigation port angle
h. Outlet shape of the balloon channel
i. The compatible cleaning brush is changed from reusable BW-7B and MH-507 to single-use BW-400B and BW-411B
j. Clarification of cleaning procedure and the brush to be used for Balloon groove
k. The shape of transducer

Validation from non-clinical testing demonstrated as defined in the performance data below show that these technological features do not raise any new issues of safety or effectiveness of the subject device.

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

Table 1.1.5-2 Comparison with Predicate Device

Item	Subject Device: BF-UC190F	Predicate Device: XBF-UC180F-DT8, K070983
General information		
Indication for Use	This instrument has been designed to be used with diagnostic ultrasound system, video system center, light source, documentation equipment, display monitor, Endo Therapy accessories such as aspiration biopsy needle. This instrument is designed for endoscopic real-time ultrasound imaging, for performing endoscopic ultrasound guided needle aspiration within the airways, tracheobronchial tree, and esophagus.	This instrument has been designed to be used with a diagnostic ultrasound system (ALOKA CO., LTD), video system center, light source, documentation equipment, video monitor, endo-therapy accessories and other ancillary equipment. This instrument is designed for endoscopic real-time ultrasonic image, ultrasound guided needle aspiration and other endoscopic procedures within the airways, tracheobronchial tree, esophagus and surrounding organs.
Clinical Application	Used with EU-ME1: - Transesophageal (non-cardiac) - Intraluminal ultrasound for upper airways and tracheobronchial tree Used with EU-ME2 / EU-ME2 PREMIR PLUS: - Transesophageal (non-cardiac) - Intraluminal ultrasound for upper airways and tracheobronchial tree	Used with SSD-Alpha5/10: - Transesophageal (non-cardiac) - Airways and tracheobronchial tree
Regulation name	Ultrasonic endoscope, its accessories and ancillary equipment	Ultrasonic Endoscope, its accessories and ancillary equipment
Regulation number	892.1550	892.1550
Product code	PSV (ultrasound bronchoscope) ITX (transducer, ultrasonic, diagnostic)	PSV (ultrasound bronchoscope) IYN (system, imaging, pulsed doppler, ultrasonic) ITX (transducer, ultrasonic, diagnostic)
Ultrasound specifications		

Nominal Ultrasonic Frequencies Of The Transducer Assembly	7-10MHz	7-10MHz

Item	Subject Device: BF-UC190F	Predicate Device: XBF-UC180F-DT8, K070983
Mode	Used with EU-ME1: B, Color doppler Used with EU-ME2 / EU-ME2 PREMIR PLUS: B, PWD, Color Doppler, Combined, Harmonic imaging	Used with SSD-Alpha5/10: B, M, PWD, Color doppler, Amplitude Doppler, Combined
Applicable Ultrasound system	EU-ME1 EU-ME2 EU-ME2 Premier Plus	ALOKA SSD-Alpha5 Diagnostic ultrasound system ALOKA SSD-Alpha10 Diagnostic ultrasound system
Scanning Direction	Parallel to the Axis of the Insertion Tube	Parallel to the Axis of the Insertion Tube
Scanning Field of View	Used with EU-ME1: 60° Used with EU-ME2 / EU-ME2 PREMIR PLUS: 65°	60°
Scanning Method	Electrical curved linear array Scanning	Electrical curved linear array Scanning
Contact Method	Balloon Method Direct contact method	Balloon Method Direct contact method
Endoscope specifications		
Field of View	80 ˚	80 ˚
Depth of Field	2 - 50mm	2 - 50mm
Direction of View	20˚ (forward-oblique)	35˚ (forward-oblique)
Outer Diameter of Distal End	φ6.6mm	φ6.9mm
Outer Diameter of Insertion Tube	φ6.3mm	φ6.2mm
Angulation UP/DOWN	160°/70°	120°/90°
Working Length	600mm	600mm
Instrument Channel	φ2.2mm	φ2.2mm
Combination use with Electrosurgical instruments	Not applicable	Not applicable
NBI observation	Not available	Not available
Scope connector	Electrical connector is integrated to scope connector. Ultrasound connecter is separated. Only when combined with the water-resistant cap, ultrasound connector is water resistant.	Electrical connector (transmit CCD image signal) and ultrasound connecter is separated. When combined with the water-resistant cap, both connecters are water resistant.
Protect water penetration during reprocessing.	US connector cap (MAJ-2295) is attached to the ultrasound cable connector on the endoscope to protect the ultrasound cable connector and the endoscope from water penetration during reprocessing.	Water resistant cap (MH-553) is attached to the ultrasound cable connector and the videoscope cable connector on the endoscope to protect the both connectors and the endoscope from water penetration during reprocessing.
Sterilization methods for reprocessing endoscope	-Ethylene oxide gas -H_2O_2 (V-PRO maX)	-Ethylene oxide gas

Item	Subject Device: BF-UC190F	Predicate Device: XBF-UC180F-DT8, K070983
Compatible Olympus reprocessor for cleaning and disinfection	Not available	Not available
High frequency accessories	Not available	Not available
RFID tag for communication with endoscope reprocessor	Available	Available
Individual scope information (Scope ID)	Available	Available
Electric safety	Comply to IEC 60601-1, IEC 60601-2-18	Comply to IEC 60601-1, IEC 60601-2-18
EMC	Comply to IEC 60601-1	Comply to IEC 60601-1

7 PERFORMANCE DATA

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

1) Ultrasound output display

The Output Display for the BF-UC190F were conducted in accordance with the FDA Guidance Document, "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." The subject device conform to the IEC 60601-2-37 Edition 2.0 2007.

2) Reprocessing validation testing

Reprocessing instruction and reprocessing method validation testing for the BF-UC190F were conducted and documentation was provided as recommended by Guidance for Industry and Food and Drug Administration Staff, "Reprocessing Medical Devices in Health Care Setting: Validation Methods and Labeling."

3) Biocompatibility testing

Biocompatibility testing for the BF-UC190F 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."

4) Software verification and validation testing

Software verification and validation testing for the BF-UC190F were conducted and documentation was 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" and "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices."

5) Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the BF-UC190F. The system complies with the ANSI/AAMI ES60601-1:2005/A2:2012/(R)2012 and IEC 60601-2-18:2009 standards for safety and the IEC 60601-1-2:2007 standards for EMC.

6) Performance testing - Bench

Bench testing for the BF-UC190F as listed below was conducted to ensure that the subject device performs as intended and meet design specifications. Device performance was assessed the design requirements, and included process verification, design verification, and design validation.

- Thermal safety test
- Mechanical durability test

7) Risk analysis

Risk analysis for the BF-UC190F was conducted in accordance with established in-house acceptance criteria based on ISO 14971:2007 and the human factors validation was conducted in accordance with the FDA Guidance, "Applying Human Factors and Usability Engineering to Medical Devices." The design verification tests and their acceptance criteria were identified and performed as a result of this risk analysis assessment.

8 CONCLUSIONS

Based on the indications for use, technological characteristics, performance testing and technological comparison to the predicate devices, the BF-UC190F raise no new issue of safety and effectiveness and are substantially equivalent to the predicate devices in terms of safety, effectiveness and performance.