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.


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,

Shu-Chen Peng

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
Indications for Use

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.

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
PRASStaff@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

1 GENERAL INFORMATION

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

- **Contact Person:** 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

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>
<thead>
<tr>
<th>Device name</th>
<th>510(k) Submitter</th>
<th>510(k) No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>XBF-UC180F-DT8 (AKA BF-UC180F)</td>
<td>OLYMPUS MEDICAL SYSTEMS CORP.</td>
<td>K070983</td>
</tr>
</tbody>
</table>
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 DEVICE

The BF-UC190F has the same technological characteristics and design as the predicate device except for the following new features:
- Outer diameter of the insertion portion
- Outer Diameter of Distal End
- Direction of view
- Angulations
- 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

<table>
<thead>
<tr>
<th>Item</th>
<th>Subject Device: BF-UC190F</th>
<th>Predicate Device: XBF-UC180F-DT8, K070983</th>
</tr>
</thead>
<tbody>
<tr>
<td>General information</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Indication for Use</td>
<td>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.</td>
<td>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.</td>
</tr>
<tr>
<td>Clinical Application</td>
<td>Used with EU-ME1:</td>
<td>Used with SSD-Alpha5/10:</td>
</tr>
<tr>
<td></td>
<td>- Transesophageal (non-cardiac)</td>
<td>- Transesophageal (non-cardiac)</td>
</tr>
<tr>
<td></td>
<td>- Intraluminal ultrasound for upper airways and tracheobronchial tree</td>
<td>- Airways and tracheobronchial tree</td>
</tr>
<tr>
<td></td>
<td>Used with EU-ME2 / EU-ME2 PREMIR PLUS:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Transesophageal (non-cardiac)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Intraluminal ultrasound for upper airways and tracheobronchial tree</td>
<td></td>
</tr>
<tr>
<td>Regulation name</td>
<td>Ultrasonic endoscope, its accessories and ancillary equipment</td>
<td>Ultrasonic Endoscope, its accessories and ancillary equipment</td>
</tr>
<tr>
<td>Regulation number</td>
<td>892.1550</td>
<td>892.1550</td>
</tr>
<tr>
<td>Product code</td>
<td>PSV (ultrasound bronchoscope)</td>
<td>PSV (ultrasound bronchoscope)</td>
</tr>
<tr>
<td></td>
<td>ITX (transducer, ultrasonic, diagnostic)</td>
<td>IYN (system, imaging, pulsed doppler, ultrasonic)</td>
</tr>
<tr>
<td></td>
<td>ITX (transducer, ultrasonic, diagnostic)</td>
<td>ITX (transducer, ultrasonic, diagnostic)</td>
</tr>
<tr>
<td>Ultrasound specifications</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nominal Ultrasonic Frequencies Of The Transducer Assembly</td>
<td>7-10MHz</td>
<td>7-10MHz</td>
</tr>
<tr>
<td>Item</td>
<td>Subject Device: BF-UC190F</td>
<td>Predicate Device: XBF-UC180F-DT8, K070983</td>
</tr>
<tr>
<td>-------------------------------------------</td>
<td>------------------------------------------------------</td>
<td>-----------------------------------------------------------------</td>
</tr>
<tr>
<td>Mode</td>
<td>Used with EU-ME1: B, Color doppler</td>
<td>Used with SSD-Alpha5/10: B, M, PWD, Color doppler, Amplitude Doppler, Combined</td>
</tr>
<tr>
<td></td>
<td>Used with EU-ME2 / EU-ME2 PREMIR PLUS: B, PWD, Color Doppler, Combined, Harmonic imaging</td>
<td></td>
</tr>
<tr>
<td>Applicable Ultrasound system</td>
<td>EU-ME1</td>
<td>ALOKA SSD-Alpha5 Diagnostic ultrasound system</td>
</tr>
<tr>
<td></td>
<td>EU-ME2</td>
<td>ALOKA SSD-Alpha10 Diagnostic ultrasound system</td>
</tr>
<tr>
<td></td>
<td>EU-ME2 Premier Plus</td>
<td></td>
</tr>
<tr>
<td>Scanning Direction</td>
<td>Parallel to the Axis of the Insertion Tube</td>
<td>Parallel to the Axis of the Insertion Tube</td>
</tr>
<tr>
<td>Scanning Field of View</td>
<td>Used with EU-ME1: 60°</td>
<td>60°</td>
</tr>
<tr>
<td></td>
<td>Used with EU-ME2 / EU-ME2 PREMIR PLUS: 65°</td>
<td></td>
</tr>
<tr>
<td>Scanning Method</td>
<td>Electrical curved linear array Scanning</td>
<td>Electrical curved linear array Scanning</td>
</tr>
<tr>
<td>Contact Method</td>
<td>Balloon Method</td>
<td>Balloon Method</td>
</tr>
<tr>
<td></td>
<td>Direct contact method</td>
<td>Direct contact method</td>
</tr>
<tr>
<td>Endoscope specifications</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Field of View</td>
<td>80 °</td>
<td>80 °</td>
</tr>
<tr>
<td>Depth of Field</td>
<td>2 - 50mm</td>
<td>2 - 50mm</td>
</tr>
<tr>
<td>Direction of View</td>
<td>20° (forward-oblique)</td>
<td>35° (forward-oblique)</td>
</tr>
<tr>
<td>Outer Diameter of Distal End</td>
<td>φ6.6mm</td>
<td>φ6.9mm</td>
</tr>
<tr>
<td>Outer Diameter of Insertion Tube</td>
<td>φ6.3mm</td>
<td>φ6.2mm</td>
</tr>
<tr>
<td>Angulation UP/DOWN</td>
<td>160°/70°</td>
<td>120°/90°</td>
</tr>
<tr>
<td>Working Length</td>
<td>600mm</td>
<td>600mm</td>
</tr>
<tr>
<td>Instrument Channel</td>
<td>φ2.2mm</td>
<td>φ2.2mm</td>
</tr>
<tr>
<td>Combination use with Electrosurgical instruments</td>
<td>Not applicable</td>
<td>Not applicable</td>
</tr>
<tr>
<td>NBI observation</td>
<td>Not available</td>
<td>Not available</td>
</tr>
<tr>
<td>Scope connector</td>
<td>Electrical connector is integrated to scope connector. Only when combined with the water-resistant cap, ultrasound connector is water resistant.</td>
<td>Electrical connector (transmit CCD image signal) and ultrasound connector is separated. When combined with the water-resistant cap, both connectors are water resistant.</td>
</tr>
<tr>
<td>Protect water penetration during reprocessing</td>
<td>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.</td>
<td>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.</td>
</tr>
<tr>
<td>Sterilization methods for reprocessing endoscope</td>
<td>-Ethylene oxide gas -H₂O₂ (V-PRO maX)</td>
<td>-Ethylene oxide gas</td>
</tr>
</tbody>
</table>

**Sterilization methods for reprocessing endoscope**: Ethylene oxide gas or Ethylene oxide gas

**Protect water penetration during reprocessing**: Use US connector cap (MAJ-2295) and water-resistant cap (MH-553) to protect the ultrasound cable connector and the endoscope from water penetration during reprocessing.
<table>
<thead>
<tr>
<th>Item</th>
<th>Subject Device: BF-UC190F</th>
<th>Predicate Device: XBF-UC180F-DT8, K070983</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compatible Olympus reprocessor for cleaning and disinfection</td>
<td>Not available</td>
<td>Not available</td>
</tr>
<tr>
<td>High frequency accessories</td>
<td>Not available</td>
<td>Not available</td>
</tr>
<tr>
<td>RFID tag for communication with endoscope reprocessor</td>
<td>Available</td>
<td>Available</td>
</tr>
<tr>
<td>Individual scope information (Scope ID)</td>
<td>Available</td>
<td>Available</td>
</tr>
<tr>
<td>Electric safety</td>
<td>Comply to IEC 60601-1, IEC 60601-2-18</td>
<td>Comply to IEC 60601-1, IEC 60601-2-18</td>
</tr>
<tr>
<td>EMC</td>
<td>Comply to IEC 60601-1</td>
<td>Comply to IEC 60601-1</td>
</tr>
</tbody>
</table>

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)


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.