August 27, 2026

Olympus Medical Systems Corporation
Wendy Perreault
Regulatory Affairs SME Consultant
Olympus Surgical Technologies of the Americas
800 W. Park Dr.
Westborough, Massachusetts 01581

Re: K260401
Trade/Device Name: Evis Eus Ultrasound Bronchofibervideoscope Olympus Bf-Ucp190f (bf-ucp190f)
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: PSV
Dated: July 29, 2026
Received: July 30, 2026

Dear Wendy Perreault:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

SHUCHEN PENG -S

Shu-Chen Peng, Ph.D.
Assistant Director
DHT1B: Division of Dental and ENT 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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260401

Please provide the device trade name(s).

EVIS EUS ULTRASOUND BRONCHOFIBERVIDEOSCOPE OLYMPUS BF-UCP190F (BF-UCP190F)

Please provide your Indications for Use below.

The EVIS EUS ULTRASOUND BRONCHOFIBERVIDEOSCOPE OLYMPUS BF-UCP190F has been designed to be used with diagnostic ultrasound system, video system center, light source, documentation equipment, display monitor, endoscopic therapy accessories such as an aspiration biopsy needle.

The EVIS EUS ULTRASOUND BRONCHOFIBERVIDEOSCOPE OLYMPUS BF-UCP190F is designed for endoscopic real-time ultrasound imaging, for performing endoscopic ultrasound guided needle aspiration within the airways and tracheobronchial tree. It is intended for use in adult patients.

Operator qualifications:
Appropriately trained healthcare professionals

Device use settings:
Professional healthcare facility (no domestic or special environments)

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

OLYMPUS

510(k) Summary: K260401

1. COMPANY INFORMATION

- **Applicant**

OLYMPUS MEDICAL SYSTEMS CORPORATION
2951 Ishikawa-cho, Hachioji-shi
Tokyo 192-8507, Japan
FDA Establishment Registration #: 8010047

- **Official Correspondent**

Wendy Perreault
c/o Olympus Surgical Technologies of the Americas
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- **Manufacturing Site**

Olympus Medical Systems Corp. Hinode Plant
34-3 Hirai, Hinode-machi, Nishitama-gun, Tokyo 1900182, Japan

- **Date Prepared:** 27-July-2026

2. PRODUCT INFORMATION

Trade Name: ULTRASOUND BRONCHOFIBERVIDEOSCOPEOLYMPUS BF-UCP190F

Common Name: Ultrasound Bronchoscope

Classification Name/Regulation Description: Ultrasonic pulsed doppler imaging system

Classification Number: 892.1550

Product Code Names: Ultrasound Bronchoscope; Transducer, ultrasonic, diagnostic

Product Codes: PSV, ITX

Regulatory Class: II

Classification Panel: Ear Nose & Throat

3. PREDICATE DEVICE

The Subject device is equivalent to the Predicate device listed below in **Table 1**.

Table 1: Predicate device of OLYMPUS BF-UCP190F

Device name	510(k) Submitter	510(k) No.
EVIS EUS ULTRASOUND BRONCHOFIBERVIDEOSCOPE OLYMPUS BF-UC190F	OLYMPUS MEDICAL SYSTEMS CORPORATION	K183525

The Predicate device has not been subject to a design-related recall.

The device in **Table 2** is used as a Reference device and has also not been subject to a design-related recall.

Table 2: Reference device of OLYMPUS BF-UCP190F

Device name	510(k) Submitter	510(k) No.
EVIS EXERA III BRONCHOFIBERVIDEOSCOPE OLYMPUS BF-MP190F	OLYMPUS MEDICAL SYSTEMS CORPORATION	K172726

4. DEVICE DESCRIPTION

The EVIS EUS ULTRASOUND BRONCHOFIBERVIDEOSCOPE OLYMPUS BF-UCP190F has been designed to be used with a diagnostic ultrasound system, video system center, light source, documentation equipment, display monitor, and endoscopic therapy accessories such as an aspiration biopsy needle. It is designed for endoscopic real-time ultrasound imaging, for performing endoscopic ultrasound-guided needle aspiration within the airways and tracheobronchial tree.

The BF-UCP190F consists of three (3) parts: the Control section, the Insertion section, and the Endoscope Connector section.

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5. INDICATIONS FOR USE

The EVIS EUS ULTRASOUND BRONCHOFIBERVIDEOSCOPE OLYMPUS BF-UCP190F has been designed to be used with diagnostic ultrasound system, video system center, light source, documentation equipment, display monitor, endoscopic therapy accessories such as an aspiration biopsy needle.

The EVIS EUS ULTRASOUND BRONCHOFIBERVIDEOSCOPE OLYMPUS BF-UCP190F is designed for endoscopic real-time ultrasound imaging, for performing endoscopic ultrasound guided needle aspiration within the airways and tracheobronchial tree. It is intended for use in adult patients.

Operator qualifications:
Appropriately trained healthcare professionals

Device use settings:
Professional healthcare facility (no domestic or special environments)

6. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

Compared to the Predicate device, the Subject device offers similar functions. A detailed comparison of the technological characteristics of the Subject and Predicate devices is provided in **Table 3** below. The differences between the devices are minor and addressed through testing, and do not raise any new issues/different questions of safety or effectiveness.

Table 3: Subject and Predicate Comparison of Technological Characteristics

	Subject Device BF-UCP190F	**Predicate Device BF-UC190F**	**How difference in technological characteristic does not raise new questions of safety and effectiveness compared to the Predicate (as applicable)**
Transducer Frequency	7-10MHz	7-10MHz	N/A; Identical to Predicate device.
Mode	Used with EU-ME3: B, FLOW, PW, THE, ELST	Used with EU-ME2: B, FLOW, PW Used with EU-ME2 PREMIER PLUS: B, FLOW, PW, THE, ELST	N/A; Identical to Predicate device.

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	Subject Device BF-UCP190F	Predicate Device BF-UC190F	How difference in technological characteristic does not raise new questions of safety and effectiveness compared to the Predicate (as applicable)
Compatible Olympus Ultrasound System	EU-ME3	EU-ME1 EU-ME2 EU-ME2 PREMIER PLUS	Compatibility is similar for Subject and Predicate devices. Compatibility between the Subject device and the compatible Ultrasound System has been verified successfully through Software, Electrical and Nonclinical Performance Testing. The difference in compatible systems does not raise new questions of safety and effectiveness.
Acoustic Output	I_{SPTA} :720 mW/cm2 or less MI :1.9 or less	I_{SPTA} :720 mW/cm2 or less MI :1.9 or less	N/A; Identical to Predicate device.
Scanning Direction	Parallel to the Axis of the Insertion Tube	Parallel to the Axis of the Insertion Tube	N/A; Identical to Predicate device.
Scanning Field of View	Used with EU-ME3 ： 65°	Used with EU-ME1 ： 60° Used with EU-ME2 and EU-ME2 PREMIER PLUS: 65°	N/A; Identical to Predicate device.
Axial resolution	1mm or less	1mm or less	N/A; Identical to Predicate device.
Lateral resolution	2mm or less	2mm or less	N/A; Identical to Predicate device.
Depth of penetration	Used with EU-ME3: 40mm or more	Used with EU-ME1 / EU-ME2 / EU-ME2 PREMIER PLUS: 40mm or more	N/A; Identical to Predicate device.
Scanning Method	Electrical curved linear array Scanning	Electrical curved linear array Scanning	N/A; Identical to Predicate device.
Ultrasound Imaging Method (Contact method)	Direct contact method	• Direct contact method • Balloon Method	Direct contact method is used by both Subject and Predicate devices; the Subject device does not support the balloon method used by the Predicate device. This difference does not affect its Substantial Equivalence to the Predicate and does not raise new questions of safety and effectiveness.
Field of View	80 ˚	80 ˚	N/A; Identical to Predicate device.
Depth of Field	2 – 50 mm	2 – 50 mm	N/A; Identical to Predicate device.

	Subject Device BF-UCP190F	Predicate Device BF-UC190F	How difference in technological characteristic does not raise new questions of safety and effectiveness compared to the Predicate (as applicable)
Direction of View	14˚ (forward-oblique)	20˚ (forward-oblique)	Direction of View is similar for Subject and Predicate devices. During insertion into the body cavity, the viewing direction of the Subject device is closer to 0 degrees compared to Predicate Device. A lower oblique angle at the distal end of an endoscope allows the user to see more area in the forward direction when inserting the endoscope into the trachea and bronchus. This allows the viewing direction and insertion direction to be more aligned for the user, improving the ease of insertion. Bench testing supports performance of the Subject device and its equivalence to the Predicate and the difference does not raise new questions of safety and effectiveness.
Optimum Working Distance	4.18 mm	5.2 mm	Similar for Subject and Predicate devices. The optimum working distance is the optimally focused distance within the range shown in Depth of Field; a difference in this value does not raise new questions of safety and effectiveness of the Subject device as supported by Performance testing.
Size of the image guide fiber	6.6 µm	6.6 µm	N/A; Identical to Predicate device.
Type of CCD Chip	Color	Color	N/A; Identical to Predicate device.
Total Number of Pixels	168096	168096	N/A; Identical to Predicate device.
Pixels per square mm	226757	226757	N/A; Identical to Predicate device.
Size of Pixel	2.1µm(H) x 2.1µm(V)	2.1µm(H) x 2.1µm(V)	N/A; Identical to Predicate device.
Active Area of CCD Chip	865.2µm(H) x 856.8µm (V)	865.2µm (H) x 856.8µm (V)	N/A; Identical to Predicate device.

	Subject Device BF-UCP190F	Predicate Device BF-UC190F	How difference in technological characteristic does not raise new questions of safety and effectiveness compared to the Predicate (as applicable)
Outer Diameter of Distal End	5.9 mm	6.6 mm	Outer diameter of Distal End is smaller in Subject device. Testing (including Reprocessing and Bench Testing [including Durability]) supports substantial equivalence of the Subject and Predicate devices, and the difference does not raise new questions of safety or effectiveness.
Outer Diameter of Insertion Tube	5.7 mm	6.3 mm	Outer diameter of the Insertion Tube is smaller in Subject device, compared to Predicate. Testing (including Reprocessing and Bench Testing [including Durability]) supports substantial equivalence of the Subject and Predicate, and the difference does not raise new questions of safety and effectiveness.
Shape of Transducer and its Housing	Housing of Transducer includes instrument channel outlet, objective lens, light guide lens, and rectangular ultrasound transducer.	Housing of Transducer includes instrument channel outlet, objective lens, light guide lens, and rectangular ultrasound transducer, as well as a balloon channel outlet and balloon grooves on the distal end of the transducer.	Shape is similar between Subject and Predicate devices. The Subject device does not support the balloon method used by the Predicate device. This difference does not raise new questions of safety and effectiveness.
Angulation UP/DOWN	170°/70°	160°/70°	The UP/DOWN Angulation is similar for the Subject and Predicate devices. This difference has been evaluated through Bench Testing (including Durability), and it does not raise new questions of safety and effectiveness.
Transducer Types	Electronic Curved Linear Array	Electronic Curved Linear Array	N/A; Identical to Predicate device.
Size and Spacing of Elements	Array Pitch = 0.17mm	Array Pitch = 0.17mm	N/A; Identical to Predicate device.
Geometrical Configuration	Curved Linear Array	Curved Linear Array	N/A; Identical to Predicate device.
Total Number of Elements	32 Elements	32 Elements	N/A; Identical to Predicate device.

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	Subject Device BF-UCP190F	Predicate Device BF-UC190F	How difference in technological characteristic does not raise new questions of safety and effectiveness compared to the Predicate (as applicable)
Array Dimensions	Elevation Aperture = 1.3mm Elevation Footprint = 1.7mm Scanplane Aperture = 5.4mm Scanplane Footprint = 5.5mm	Elevation Aperture = 1.3mm Elevation Footprint = 1.7mm Scanplane Aperture = 5.4mm Scanplane Footprint = 5.5mm	N/A; Identical to Predicate device.
Insertion section working length	600 mm	600 mm	N/A; Identical to Predicate device.
Inner Diameter of Instrument Channel	1.7 mm	2.2 mm	Inner Diameter is similar for the Subject and Predicate devices. Reprocessing and Bench Testing (including Durability) support performance of the Subject device and the slight difference in inner diameter does not raise new questions of safety and effectiveness.
Distal end	Polytetrafluoroethylene	Polytetrafluoroethylene	N/A; Identical to Predicate device.
Rubber adhesive	ES-19MC	ES-19MC	N/A; Identical to Predicate device.
Scope connector	The electrical connector is integrated into the scope connector. The ultrasound connector is separated. The ultrasound connector is only water-resistant when the compatible water-resistant Ultrasound Connector Cap is connected.	The electrical connector is integrated into the scope connector. The ultrasound connector is separated. The ultrasound connector is only water-resistant when the compatible water-resistant Ultrasound Connector Cap is connected.	N/A; Identical to Predicate device.
Method of protection from water penetration during reprocessing	The Ultrasound 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.	The Ultrasound 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.	N/A; Identical to Predicate device.

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	Subject Device BF-UCP190F	Predicate Device BF-UC190F	How difference in technological characteristic does not raise new questions of safety and effectiveness compared to the Predicate (as applicable)
Sterilization methods for reprocessing endoscope	• Ethylene oxide gas • H2O2 (V-PRO maX, V-PRO maX 2, STERRAD NX/100NX/100S)	• Ethylene oxide gas • H2O2 (V-PRO maX)	Similar for Subject and Predicate devices. All Reprocessing methods (including the Sterilizer/ Sterilization process) are validated in accordance with FDA Guidance and Recognized Consensus Standards. The differences in H2O2 sterilization systems do not affect substantial equivalence of the Subject and Predicate devices and do not raise new questions of safety and effectiveness.
Compatible Olympus Reprocessor for cleaning and disinfection	OER-Elite	OER-Elite	N/A; Identical to Predicate device.
RFID tag for communication with endoscope Reprocessor	Available	Available	N/A; Identical to Predicate device.
Individual scope information (Scope ID)	Available	Available	N/A; Identical to Predicate device.
Total number of the Image guide fibers	5500	10000	Subject device has fewer Image guide fibers than Predicate device. Resolution testing supports the performance of the Subject device, and the difference does not affect its substantial equivalence to the Predicate or raise new questions of safety and effectiveness.
Materials	Fluorine Resin, Fluoro rubber, Epoxy, Silicone rubber, Polypheylsulfone, Polytetrafluoroethylene, Stainless Steel, Glass, Anti-reflection coating, Polytetrafluoro-ethylene, Silver brazes	Fluorine Resin, Fluoro rubber, Epoxy, Silicone rubber, Polypheylsulfone, Polytetrafluoroethylene, Stainless Steel, Glass, Anti-reflection coating, Polytetrafluoro-ethylene, Silver brazes	Similar for Subject and Predicate devices. The Subject and Predicate devices both use Fluoro Rubber, but they have different grade names (GR 1005 or GR 1003). Biocompatibility, Bench testing (including durability), and Reprocessing testing support the substantial equivalence of the two devices, and the difference does not raise any new questions of safety or effectiveness.

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7. SUMMARY OF NON-CLINICAL PERFORMANCE DATA

Results of the following testing support the safety and performance of the Subject device and demonstrate its equivalence to the Predicate device; all testing passed/met the acceptance criteria, demonstrated compliance with the cited standards and FDA Guidance shown below, and supported equivalent safety and performance to the Predicate device:

- Performance Testing – Bench Testing (including Acoustic Output in compliance with IEC 60601-2-37, IEC 62359, IEC 62127-1, and FDA Guidance: *Marketing Clearance of Diagnostic Ultrasound Systems and Transducers - Guidance for Industry and Food and Drug Administration Staff* [February 21, 2023]; Clinical Accuracy; Color Performance; Depth of Field; Direction of View / Field of View; Distortion; Durability; Image Intensity Uniformity; Noise and Dynamic Range; Photobiological Safety; Resolution; Strain Ratio; Suction Capability; Thermal Safety; Transducer Element Check; and Human Use Factors following FDA Guidance Documents *Applying Human Factors and Usability Engineering to Medical Devices: Guidance for Industry and Food and Drug Administration Staff* [issued February 3, 2016] and *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance for Industry and Food and Drug Administration Staff* [issued March 17, 2015]).
- Biocompatibility Testing in accordance with FDA Guidance *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"* (ISO 10993-1; ISO 10993-5; ISO 10993-10; ISO 10993-11, ISO 10993-12; ISO 10993-17; ISO 10993-18; ISO 10993-23; USP Chapter <151>)
- Reprocessing Validation (AAMI TIR12; ANSI AAMI ST58; ANSI AAMI ST98; ISO 11135; ISO 11138-2; ISO 14937; ISO 10993-7)
- Electrical Safety/EMC Testing (IEC 60601-1; IEC ES60601-1; IEC 60601-1-2; IEC 60601-2-18; IEC 60601-2-37; IEC TR 60601-4-2)
- Software and Cybersecurity Testing (The BF-UCP190F software was developed in compliance with the FDA guidance document titled *Content of Premarket Submissions for Device Software Functions – Guidance for Industry and Food and Drug Administration Staff* issued on June 14, 2023, and Enhanced Documentation is provided for the Subject device. Cybersecurity for the device was implemented in compliance with the FDA guidance document titled *Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions – Guidance for Industry and Food and Drug Administration Staff*, issued on September 27, 2023.)

8. SUMMARY OF CLINICAL PERFORMANCE DATA

No clinical data was collected to support performance of the Subject device.

9. CONCLUSION

The results of non-clinical performance testing demonstrate that the Subject device is as safe and effective as the Predicate device to support a substantial equivalence determination.