April 23, 2026

Olympus Medical Systems Corp.
Teffany Hutto
Project Manager, Regulatory Affairs
Olympus Corporation of the Americas
800 West Park Drive
Westborough, Massachusetts 01581

Re: K252341
Trade/Device Name: Evis Exera III Bronchovideoscope (Olympus BF-Q190); Evis Exera III Bronchovideoscope (Olympus BF-H190); Evis Exera III Bronchovideoscope (Olympus BF-1TH190)
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: March 24, 2026
Received: March 24, 2026

Dear Teffany Hutto:

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,

JOYCE C. LIN -S

for 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252341

Device Name
EVIS EXERA III BRONCHOVIDEOSCOPE (OLYMPUS BF-Q190);
EVIS EXERA III BRONCHOVIDEOSCOPE (OLYMPUS BF-H190);
EVIS EXERA III BRONCHOVIDEOSCOPE (OLYMPUS BF-1TH190)

Indications for Use *(Describe)*
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.

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Date Prepared: April 23, 2026

510(k) Summary

K252341

1. GENERAL INFORMATION

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

■ Contact Person: Teffany Hutto
Olympus Corporation of the Americas
3500 Corporate Parkway PO Box 610
Center Valley, PA 18034-0610, USA
Phone: 512-508-6550
Fax: 484-896-7128
Email: teffany.hutto@olympus.com

■ Manufacturing site: Aizu Olympus Co., Ltd.,
3-1-1 Niiderakita, Aizuwakamatsu-shi, Fukushima 965-8520, Japan

2. DEVICE IDENTIFICATION

Trade/Device Name	EVIS EXERA III Bronchovideoscope BF-Q190
Model Name	BF-Q190
Common Name	Bronchovideoscope
Regulation Number	874.4680
Regulation Name	Bronchoscope (flexible or rigid) and accessories
Regulatory Class	II
Product Code	EOQ (Bronchoscope (Flexible or rigid)) NWB (Endoscope, Accessories, Narrow Band Spectrum)
Classification Panel	Ear, Nose and Throat

Trade/Device Name	EVIS EXERA III Bronchovideoscope BF-H190
Model Name	BF-H190
Common Name	Bronchovideoscope
Regulation Number	874.4680
Regulation Name	Bronchoscope (flexible or rigid) and accessories
Regulatory Class	II
Product Code	EOQ (Bronchoscope (Flexible or rigid)) NWB (Endoscope, Accessories, Narrow Band Spectrum)
Classification Panel	Ear, Nose and Throat

Trade/Device Name	EVIS EXERA III Bronchovideoscope BF-1TH190
Model Name	BF-1TH190
Common Name	Bronchovideoscope
Regulation Number	874.4680
Regulation Name	Bronchoscope (flexible or rigid) and accessories
Regulatory Class	II
Product Code	EOQ (Bronchoscope (Flexible or rigid)) NWB (Endoscope, Accessories, Narrow Band Spectrum)
Classification Panel	Ear, Nose and Throat

3. PREDICATE DEVICES

Device name	510(k) Submitter	510(k) No.
EVIS EXERA III BRONCHOVIDEOSCOPE BF-Q190, BF-H190, BF-1TH190	OLYMPUS MEDICAL SYSTEMS CORP.	K121959

4. DEVICE DESCRIPTION

The EVIS EXERA III BRONCHOVIDEOSCOPES (OLYMPUS BF-Q190, OLYMPUS BF-H190, and BF-1TH190) are used for endoscopic diagnosis and treatment within the respiratory organs. These endoscopes consist of three parts: the control section, the insertion section, and the connector section.

5. 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.

1) Control section

The UP/DOWN angulation control knob and the RIGHT/LEFT angulation control knob 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 knob and the RIGHT/LEFT angulation control knob, the bending section at the distal end bends vertically or parallel to guide the distal end for insertion and observation.

The observation mode can be selected by focus switching function, “near focus mode” featuring ground-breaking resolving power for close observation or “normal focus mode” for normal observation. To realize the dual focus mechanism, Voice Coil Motor (VCM) is incorporated as an actuator.

The endoscope contains a cylinder to attach a suction valve for suction and air/water valve. Depressing the suction valve will allow the physician 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. Depressing the air/water valve will allow the doctor to feed water through the endoscope for lens washing. It also can be operated to feed air for removing any fluids or debris adhering to the objective lens.

2) Insertion section

The insertion section has main parts including the image guide, light guides that bring light from the video system center through the endoscope, and instrument channel where therapeutic tools can be pushed in and out (also the suction channel).

3) Connector section

The connector section connects the endoscope with the video system center (CV-1500) through the universal cord.

6. INDICATIONS FOR USE

EVIS EXERA III BRONCHOVIDEOSCOPE (OLYMPUS BF-Q190, OLYMPUS BF-H190, and OLYMPUS BF-1TH190) 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.

INDICATIONS FOR USE COMPARISON

The Indications for Use for the Subject Device is exactly the same as the Indications for Use for the Predicate Device.

7. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

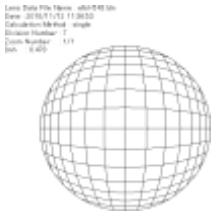
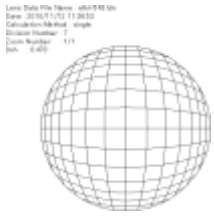
The subject devices have the same technological characteristics and design as the applicable predicate devices. There have been no modifications from the prior clearances of these devices including:

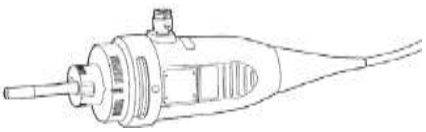
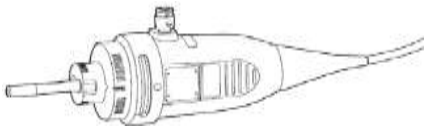
- Design
- Materials
- Sterilization
- Shelf Life
- Reprocessing
- Packaging
- Software

This 510(k) is a notification to communicate an update to the Operation Manual to provide new instructions on the proper use of the subject devices with laser, high frequency, and Argon Plasma Coagulation (APC) systems.

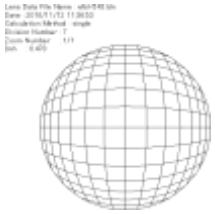
A side-by-side comparison of the subject device and the predicate device is provided below.

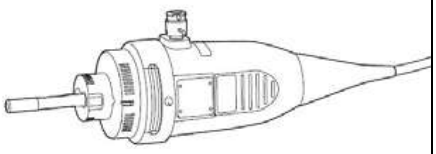
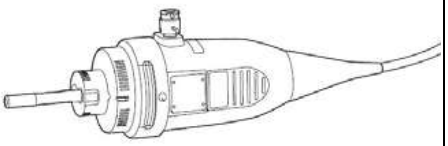
BF-Q190

Specifications		Subject device BF-Q190	Predicate device BF-Q190
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.	
Common name		BRONCHOVIDEOSCOPE	BRONCHOVIDEOSCOPE
Regulation name		Bronchoscope (flexible or rigid) and accessories	Bronchoscope (flexible or rigid) and accessories
Regulation number		874.4680	874.4680
Product code		EOQ, EOB, NWB	EOQ, EOB, NWB
Classification panel		Ear Nose & Throat	Ear Nose & Throat
Sterilization		Ethylene oxide sterilization STERRAD NX	Ethylene oxide sterilization STERRAD NX
Specifications			
Image capture system	1 Field of View	120°	120°
	2 Depth of Field	3-100mm	3-100mm
	3 Standard Focal Length	0.558mm	0.558mm
	4 Optimum Working Distance	5.7mm	5.7mm
	5 Direction of View	0°(Forward viewing)	0°(Forward viewing)
	6 Highest Resolution	15.85 line air/mm(Typical)	15.85 line pair/mm(Typical)
	7 Distortion		
	8 Magnification of Objective Lens (at Optimum)	0.093	0.093
	9 F# of Objective Lens (at Optimum)	5.066	5.066
	10 Total Number of Pixels	168,096	168,096

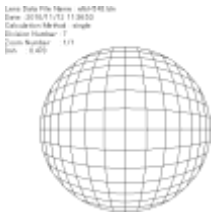
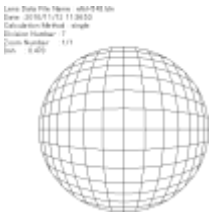
Specifications		Subject device BF-Q190	Predicate device BF-Q190
	11 Pixels per square mm	226,757	226,757
	12 Size of Pixel	2.1μm(H) x 2.1μm(V)	2.1μm(H) x 2.1μm(V)
	13 Active Area of CCD Chip	0.8652mm(H) x 0.8568mm(V)	0.8652mm(H) x 0.8568mm(V)
	14 Type of CCD Chip	Color	Color
	Outer Diameter of Distal End	φ4.8mm	φ4.8mm
	Outer Diameter of Insertion Tube	φ6.0mm	φ6.0mm
	Angulation UP/DOWN	UP:210°, DOWN:130°	UP:210°, DOWN:130°
	Working Length	600mm	600mm
	Inner Diameter of Instrument Channel	φ2.0mm	φ2.0mm
	Number of Light guide fibers	820	820
	NBI observation	Available	Available
	Insertion tube rotation	240 deg.	240 deg.
Scope Connector		Water Resistant One Touch Connector 	Water Resistant One Touch Connector 

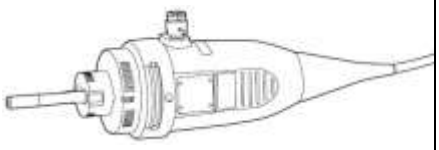
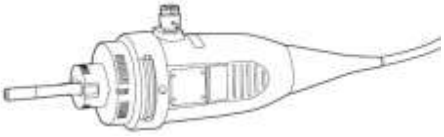
BF-H190

Specifications		Subject device BF-H190	Predicate device BF-H190
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.	
Common name		BRONCHOVIDEOSCOPE	BRONCHOVIDEOSCOPE
Regulation name		Bronchoscope (flexible or rigid) and accessories	Bronchoscope (flexible or rigid) and accessories
Regulation number		874.4680	874.4680
Product code		EOQ, EOB, NWB	EOQ, EOB, NWB
Classification panel		Ear Nose & Throat	Ear Nose & Throat
Sterilization		Ethylene oxide sterilization STERRAD NX	Ethylene oxide sterilization STERRAD NX
Specifications			
Image capture system	1 Field of View	120°	120°
	2 Depth of Field	3-100mm	3-100mm
	3 Standard Focal Length	0.946mm	0.946mm
	4 Optimum Working Distance	6.5mm	6.5mm
	5 Direction of View	0°(Forward viewing)	0°(Forward viewing)
	6 Highest Resolution	17.78 line pair/mm(Typical)	17.78 line pair/mm(Typical)
	7 Distortion		
	8 Magnification of Objective Lens (at Optimum)	0.138	0.138
	9 F# of Objective Lens (at Optimum)	7.88	7.88
	10 Total Number of Pixels	492,980	492,980

Specifications		Subject device BF-H190	Predicate device BF-H190
	11 Pixels per square mm	226,757	226,757
	12 Size of Pixel	2.1μm(H) x 2.1μm(V)	2.1μm(H) x 2.1μm(V)
	13 Active Area of CCD Chip	1.674mm(H) x 1.336mm(V)	1.674mm(H) x 1.336mm(V)
	14 Type of CCD Chip	Color	Color
	Outer Diameter of Distal End	φ5.5mm	φ5.5mm
	Outer Diameter of Insertion Tube	φ6.6mm	φ6.6mm
	Angulation UP/DOWN	UP:210°, DOWN:130°	UP:210°, DOWN:130°
	Working Length	600mm	600mm
	Inner Diameter of Instrument Channel	φ2.0mm	φ2.0mm
	Number of Light guide fibers	1200	1200
	NBI observation	Available	Available
	Insertion tube rotation	240 deg.	240 deg.
Scope Connector		Water Resistant One Touch Connector 	Water Resistant One Touch Connector 

BF-1TH190

Specifications		Subject device BF-1TH190	Predicate device BF-1TH190
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.	
Common name		BRONCHOVIDEOSCOPE	BRONCHOVIDEOSCOPE
Regulation name		Bronchoscope (flexible or rigid) and accessories	Bronchoscope (flexible or rigid) and accessories
Regulation number		874.4680	874.4680
Product code		EOQ, EOB, NWB	EOQ, EOB, NWB
Classification panel		Ear Nose & Throat	Ear Nose & Throat
Sterilization		Ethylene oxide sterilization STERRAD NX	Ethylene oxide sterilization STERRAD NX
Specifications			
Image capture system	1 Field of View	120°	120°
	2 Depth of Field	3-100mm	3-100mm
	3 Standard Focal Length	0.946mm	0.946mm
	4 Optimum Working Distance	6.5mm	6.5mm
	5 Direction of View	0°(Forward viewing)	0°(Forward viewing)
	6 Highest Resolution	17.78 line pair/mm(Typical)	17.78 line pair/mm(Typical)
	7 Distortion		
	8 Magnification of Objective Lens (at Optimum)	0.138	0.138
	9 F# of Objective Lens (at Optimum)	7.88	7.88
	10 Total Number of Pixels	492,980	492,980

Specifications		Subject device BF-1TH190	Predicate device BF-1TH190
	11 Pixels per square mm	226,757	226,757
	12 Size of Pixel	2.1μm(H) x 2.1μm(V)	2.1μm(H) x 2.1μm(V)
	13 Active Area of CCD Chip	1.674mm(H) x 1.336mm(V)	1.674mm(H) x 1.336mm(V)
	14 Type of CCD Chip	Color	Color
	Outer Diameter of Distal End	φ6.2mm	φ6.2mm
	Outer Diameter of Insertion Tube	φ7.2mm	φ7.2mm
	Angulation UP/DOWN	UP:180°, DOWN:130°	UP:180°, DOWN:130°
	Working Length	600mm	600mm
	Inner Diameter of Instrument Channel	φ2.8mm	φ2.8mm
	Number of Light guide fibers	1200	1200
	NBI observation	Available	Available
	Insertion tube rotation	240 deg.	240 deg.
Scope Connector		Water Resistant One Touch Connector 	Water Resistant One Touch Connector 

8. PERFORMANCE DATA

The following performance data were provided in support of the labeling change to address the proper use of the subject devices with laser, high frequency, and APC systems.

1) Performance testing - Bench

Bench testing as listed below was conducted to ensure that the subject device performs as intended and meet design specifications.

- Ignition Factors Safety Study (Laser)
- Ignition Factors Safety Study (High-Frequency)
- Ignition Factors Safety Study (APC)
- Ignition Factors Safety Study (Scope Comparison)
- Human Factors Validation Testing

2) Performance testing – Animal/Clinical

Animal and clinical testing were not performed.

3) Risk management

Risk management was performed in accordance with ISO 14971:2019. The design verification tests and their acceptance criteria were performed and identified as a result of this risk management.

4) Testing not completed

Since there were no design, material, sterilization, reprocessing, packaging, shelf life, or software changes, the following testing was not performed:

- Biocompatibility Testing
- Sterilization / Reprocessing
- Shelf Life
- Stability Testing
- Package Integrity Test
- Software Testing and Cybersecurity
- Electrical Safety and EMC
- Residual Toxicity of Reprocessing Chemicals
- Clinical

9. CONCLUSIONS

Based on the indications for use, technological characteristics, performance testing and technological comparison to the predicate device, EVIS EXERA III BRONCHOVIDEOSCOPES (OLYMPUS BF-Q190, OLYMPUS BF-H190, and BF-1TH190) raise no new questions of safety and effectiveness and are substantially equivalent to the predicate devices in terms of safety, effectiveness, and performance.