June 23, 2025

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

Re: K250862
Trade/Device Name: Evis Exera IIi Bronchovideoscope (olympus Bf-xp190); Evis Exera IIi Bronchovideoscope (olympus Bf-p190); Evis Exera IIi Bronchovideoscope (olympus Bf-xt190); Bronchovideoscope (olympus Bf-h1100); Bronchovideoscope (olympus Bf-1th1100)
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: May 29, 2025
Received: May 29, 2025

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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.	K250862

Please provide the device trade name(s).

EVIS EXERA III BRONCHOVIDEOSCOPE (OLYMPUS BF-XP190);
EVIS EXERA III BRONCHOVIDEOSCOPE (OLYMPUS BF-P190);
EVIS EXERA III BRONCHOVIDEOSCOPE (OLYMPUS BF-XT190);
BRONCHOVIDEOSCOPE (OLYMPUS BF-H1100);
BRONCHOVIDEOSCOPE (OLYMPUS BF-1TH1100)

Please provide your Indications for Use below.

EVIS EXERA III BRONCHOVIDEOSCOPES OLYMPUS BF-XP190 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 BRONCHOVIDEOSCOPES 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. This instrument is indicated for use within the airways and tracheobronchial tree.

EVIS EXERA III BRONCHOVIDEOSCOPES OLYMPUS BF-XT190 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.

BRONCHOVIDEOSCOPE OLYMPUS BF-H1100 is intended to be used with an Olympus video system center, 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.

BRONCHOVIDEOSCOPE OLYMPUS BF-1TH1100 is intended to be used with an Olympus video system center, 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.

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

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

Date Prepared: April 21, 2025

510(k) Summary

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-XP190
Model Name	BF-XP190
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-P190
Model Name	BF-P190
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-XT190
Model Name	BF-XT190
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	Bronchovideoscope BF-H1100
Model Name	BF-H1100
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	Bronchovideoscope BF-1TH1100
Model Name	BF-1TH1100
Common Name	Bronchovideoscope
Product Code	EOQ (Bronchoscope (Flexible or rigid)) NWB (Endoscope, Accessories, Narrow Band Spectrum)
Regulation Name	Bronchoscope (flexible or rigid) and accessories
Regulatory Class	II
Product Code	EOQ (Bronchoscope (Flexible or rigid))
Classification Panel	Ear, Nose and Throat

3. PREDICATE DEVICES

- **Predicate devices (BF-XP190, BF-P190 and BF-XT190)**

Device name	510(k) Submitter	510(k) No.
EVIS EXERA III BRONCHOVIDEOSCOPE BF-P190, BF-XP190	OLYMPUS MEDICAL SYSTEMS CORP.	K201758
EVIS EXERA III BRONCHOVIDEOSCOPE BF-XT190	OLYMPUS MEDICAL SYSTEMS CORP	K183419

- **Reference devices (BF-XP190, BF-P190 and BF-XT190)**

Device name	510(k) Submitter	510(k) No.
BRONCHOVIDEOSCOPE OLYMPUS BF-H1100	OLYMPUS MEDICAL SYSTEMS CORP.	K222861
BRONCHOVIDEOSCOPE OLYMPUS BF-1TH1100	OLYMPUS MEDICAL SYSTEMS CORP	K222861

- **Predicate devices (BF-H1100 and BF1TH1100)**

Device name	510(k) Submitter	510(k) No.
BRONCHOVIDEOSCOPE OLYMPUS BF-H1100	OLYMPUS MEDICAL SYSTEMS CORP.	K222861
BRONCHOVIDEOSCOPE OLYMPUS BF-1TH1100	OLYMPUS MEDICAL SYSTEMS CORP	K222861

4. DEVICE DESCRIPTION

The EVIS EXERA III BRONCHOVIDEOSCOPES (OLYMPUS BF-XP190, OLYMPUS BF-P190, and BF-XT190) and BRONCHOVIDEOSCOPE BF-H1100 and BF-1TH1100 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 BRONCHOVIDEOSCOPES OLYMPUS BF-XP190 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 BRONCHOVIDEOSCOPES 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. This instrument is indicated for use within the airways and tracheobronchial tree.

EVIS EXERA III BRONCHOVIDEOSCOPES OLYMPUS BF-XT190 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.

BRONCHOVIDEOSCOPE OLYMPUS BF-H1100 is intended to be used with an Olympus video system center, 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.

BRONCHOVIDEOSCOPE OLYMPUS BF-1TH1100 is intended to be used with an Olympus video system center, 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 equivalent Predicate Device.

7. COMPARISON OF TECHNOLOGY 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

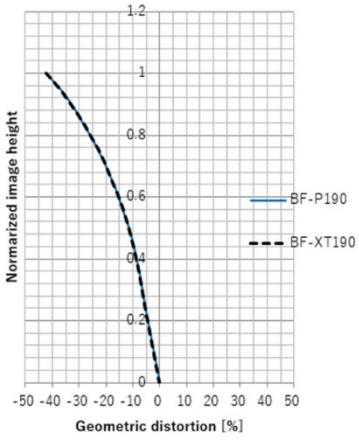
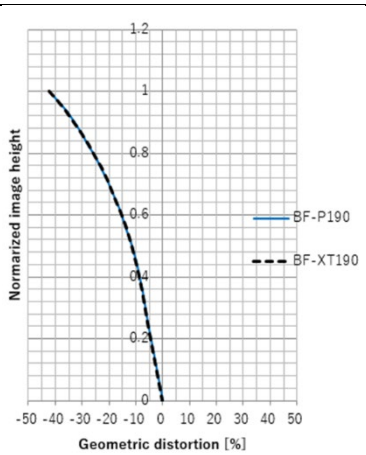
This 510(k) is to request clearance for use of the BF-XP190, BF-P190, and BF-XT-190 scopes with the recently cleared EVIS X1 VIDEO SYSTEM CENTER CV-1500 under K222861. The BF-XP190, BF-P190, and BF-XT-190 scopes will be used with imaging modes WLI, NBI, RDI, TXI, and BAI-MAC.

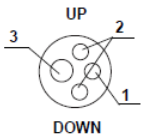
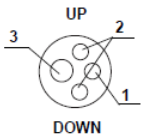
This 510(k) will also request clearance to update the labeling to include new instructions on proper use of these scopes, along with the other subject devices, with laser, high frequency, and APC systems for all Subject Devices (BF-P190, BF-XP190, BF-XT190, BF-H1100, and BF-1TH1100)

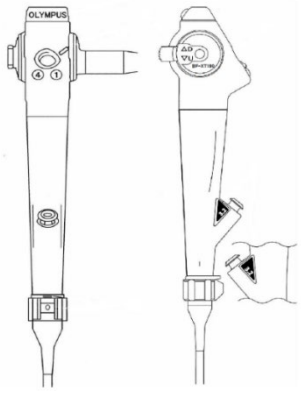
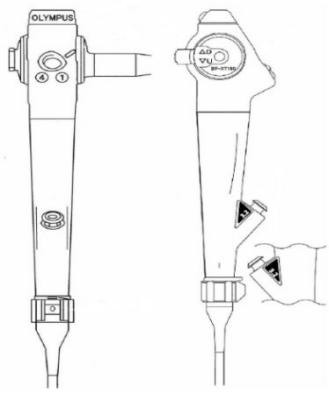
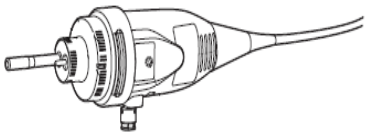
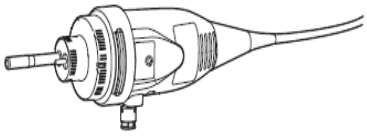
A side-by-side comparison of the subject device and the predicate device is provided below.

Table 1 – BF-P190

Item	**Subject Device**	**Predicate Device**
	BF-P190 (combination with CV-1500)	**BF-P190 (combination with CV-190/CLV-190)**
	TBD	**K201758**
Regulation Number	874.4680	874.4680
Regulatory Class	Class II	Class II
Product Code	EOQ; Bronchoscope (Flexible Or Rigid)	EOQ; Bronchoscope (Flexible Or Rigid)
Review Panel	Ear Nose and Throat	Ear Nose and Throat
Common name	BRONCHOSCOPE	BRONCHOSCOPE
Manufacturer	OLYMPUS MEDICAL SYSTEMS CORP.	OLYMPUS MEDICAL SYSTEMS CORP.

Item	Subject Device	Predicate Device
	BF-P190 (combination with CV-1500)	**BF-P190 (combination with CV-190/CLV-190)**
	TBD	**K201758**
Indications for Use	The EVIS EXERA III Bronchovideoscopes BF-P190 are 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.
Use Environment	Healthcare facility/hospital	Healthcare facility/hospital
Single-Use/Reuse	Reusable	Reusable
Duration and type of contact	Surface-contacting device in contact with mucosal membranes. The contact duration is limited exposure (<24 hrs).	Surface-contacting device in contact with mucosal membranes. The contact duration is limited exposure (<24 hrs).
Depth of Field	2 - 50 mm	2 - 50 mm
Direction of Forward View	0° (Forward viewing)	0° (Forward viewing)
Field of View(FOV)	110°	110°
Distortion		
Magnification of Objective Lens at Optimum Working Distance	0.017	0.017
Pixels per square mm	226,760	226,760
Active Area of CCD Chip	(H)477μm×(V)468μm	(H)477μm×(V)468μm
Total Number of Pixels	50,621	50,621
Size of Pixel	(H)2.1μm×(V)2.1μm	(H)2.1μm×(V)2.1μm

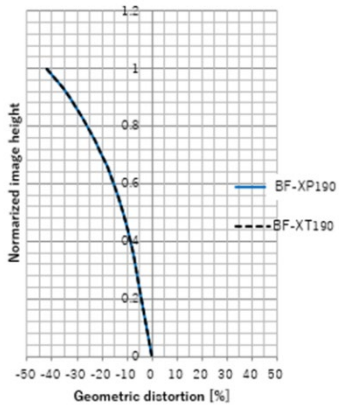
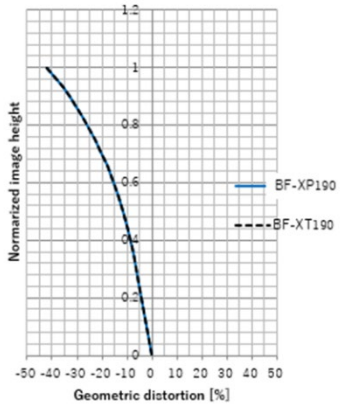
Item		Subject Device	Predicate Device
		BF-P190 (combination with CV-1500)	BF-P190 (combination with CV-190/CLV-190)
		TBD	K201758
Type of CCD Chip		Color	Color
Narrow Band Image (NBI) observation		Available	Available
Red Dichromatic Imaging (RDI) observation		Available	Not Available
Pre-freeze function		Available	Available
Electronic zoom function		Not Available	Not Available
Electronic shutter function		Not Available	Not Available
Records of endoscope's information		Available	Available
Outer Diameter of Distal End		Φ4.2mm	Φ4.2mm
Outer Diameter of Insertion Tube		Φ4.1mm	Φ4.1mm
Bending Section Angulation		UP:210°, DOWN:130°	UP:210°, DOWN:130°
Working Length		600mm	600mm
Instrument Channel inner diameter [mm]		φ2.0	φ2.0
Distal end enlarged		 1 Objective lens 2 Light guide lens 3 Instrument channel outlet	 1 Objective lens 2 Light guide lens 3 Instrument channel outlet
Total Length		880mm	880mm
Minimum visible distance		3mm	3mm
Direction from which EndoTherapy accessories enter and exit the endoscopic image			
Material	Insertion Tube (Outer layer)	Fluoro Resin (F-COAT-KAI)	Fluoro Resin (F-COAT-KAI)
	Bending section rubber	Fluoro Rubber (GR1005)	Fluoro Rubber (GR1005)

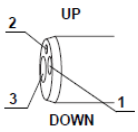
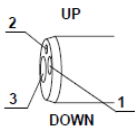
Item		Subject Device	Predicate Device
		BF-P190 (combination with CV-1500)	BF-P190 (combination with CV-190/CLV-190)
		TBD	K201758
	Adhesive on the bending rubber	Epoxy Glue (ES-19MC)	Epoxy Glue (ES-19MC)
	Distal end adhesive	Epoxy Glue (ES-19MC)	Epoxy Glue (ES-19MC)
	Instrument channel	Polytetrafluoro-ethylene	Polytetrafluoro-ethylene
	Distal end	Polysulfone (P1700-216)	Polysulfone (P1700-216)
	Objective lens	Glass (Sapphire)	Glass (Sapphire)
	Light guide lens	Glass (OHARA S-LAH58)	Glass (OHARA S-LAH58)
Control section			
Configuration of Control section and location of scope switch			
The insertion tube rotation angle by simply turning a ring on the control section of the scope.		left or right up to 120°	left or right up to 120°
Video connection section			
Scope connector		Water resistant one-touch connector	Water resistant one-touch connector
Configuration of Video connection section and Light guide connector section			
Software			
Correction of pixel defect		Have	Have
Scope information			

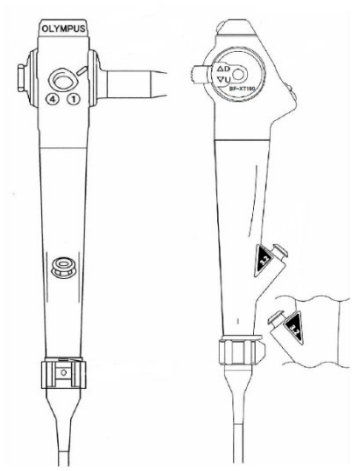
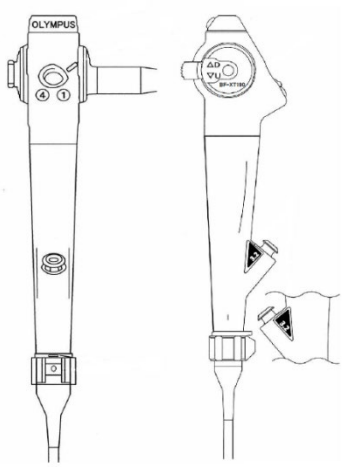
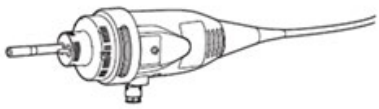
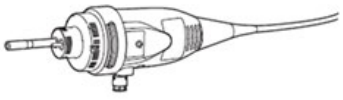
Item	Subject Device	Predicate Device
	BF-P190 (combination with CV-1500)	BF-P190 (combination with CV-190/CLV-190)
	TBD	K201758
Individual scope information (Scope ID)	Have	Have
Compatibility of endotherapy accessories		
High frequency treatment accessories	Available	Available
Laser treatment accessories	Not Available	Not Available
Other		
Total weight	840g	840g

Table 2 – BF-XP190

Item	Subject Device	Predicate Device
	BF-XP190 (combination with CV-1500)	BF-XP190 (combination with CV-190/CLV-190)
	TBD	K201758
Regulation Number	874.4680	874.4680
Regulatory Class	Class II	Class II
Product Code	EOQ; Bronchoscope (Flexible Or Rigid)	EOQ; Bronchoscope (Flexible Or Rigid)
Review Panel	Ear Nose and Throat	Ear Nose and Throat
Common name	BRONCHOSCOPE	BRONCHOSCOPE
Manufacturer	OLYMPUS MEDICAL SYSTEMS CORP.	OLYMPUS MEDICAL SYSTEMS CORP.
Indications for Use	The EVIS EXERA III Bronchovideoscopes BF-XP190 are 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-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.
Use Environment	Healthcare facility/hospital	Healthcare facility/hospital
Single-Use/Reuse	Reusable	Reusable

Item	Subject Device	Predicate Device
	BF-XP190 (combination with CV-1500)	BF-XP190 (combination with CV-190/CLV-190)
	TBD	K201758
Duration and type of contact	Surface-contacting device in contact with mucosal membranes. The contact duration is limited exposure (<24 hrs).	Surface-contacting device in contact with mucosal membranes. The contact duration is limited exposure (<24 hrs).
Depth of Field	2 - 50 mm	2 - 50 mm
Direction of Forward View	0° (Forward viewing)	0° (Forward viewing)
Field of View(FOV)	110°	110°
Distortion		
Magnification of Objective Lens at Optimum Working Distance	0.017	0.017
Pixels per square mm	226,760	226,760
Active Area of CCD Chip	(H)477μm×(V)468μm	(H)477μm×(V)468μm
Total Number of Pixels	50,621	50,621
Size of Pixel	(H)2.1μm×(V)2.1μm	(H)2.1μm×(V)2.1μm
Type of CCD Chip	Color	Color
Narrow Band Image (NBI) observation	Available	Available
Red Dichromatic Imaging (RDI) observation	Available	Not Available
Pre-freeze function	Available	Available
Electronic zoom function	Not Available	Not Available
Electronic shutter function	Not Available	Not Available
Records of endoscope's information	Available	Available

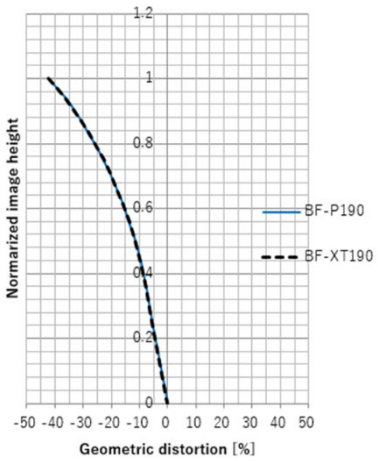
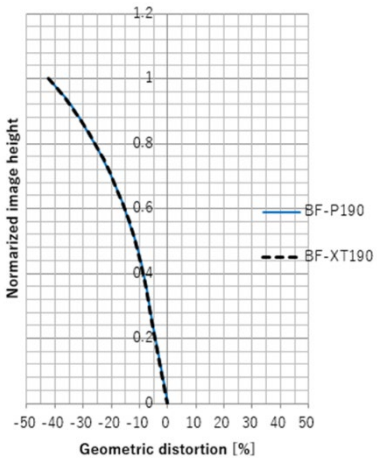
Item		Subject Device	Predicate Device
		BF-XP190 (combination with CV-1500)	BF-XP190 (combination with CV-190/CLV-190)
		TBD	K201758
Outer Diameter of Distal End		Φ3.1 mm (Tapered part of distal tip: ø 2.9 mm)	Φ3.1 mm (Tapered part of distal tip: ø 2.9 mm)
Outer Diameter of Insertion Tube		Φ2.8 mm	Φ2.8 mm
Bending Section Angulation		UP:210°, DOWN:130°	UP:210°, DOWN:130°
Working Length		600mm	600mm
Instrument Channel inner diameter [mm]		φ1.2	φ1.2
Distal end enlarged		 1 Objective lens 2 Light guide lens 3 Instrument channel outlet	 1 Objective lens 2 Light guide lens 3 Instrument channel outlet
Total Length		880mm	880mm
Minimum visible distance		3mm	3mm
Direction from which EndoTherapy accessories enter and exit the endoscopic image			
Material	Insertion Tube (Outer layer)	Fluoro Resin (F-COAT-KAI	Fluoro Resin (F-COAT-KAI)
	Bending section rubber	Fluoro Rubber (GR1005)	Fluoro Rubber (GR1005)
	Adhesive on the bending rubber	Epoxy Glue (ES-19MC)	Epoxy Glue (ES-19MC)
	Distal end adhesive	Epoxy Glue (ES-19MC)	Epoxy Glue (ES-19MC)
	Instrument channel	Polytetrafluoro-ethylene	Polytetrafluoro-ethylene
	Distal end	Steel (SUS303)	Steel (SUS303)
	Objective lens	Glass (Sapphire)	Glass (Sapphire)
	Light guide lens	Glass (OHARA S-LAH58)	Glass (OHARA S-LAH58)

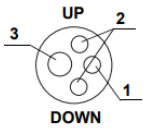
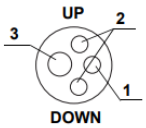
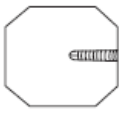
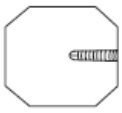
Item	Subject Device	Predicate Device
	BF-XP190 (combination with CV-1500)	BF-XP190 (combination with CV-190/CLV-190)
	TBD	K201758
Control section		
Configuration of Control section and location of scope switch		
The insertion tube rotation angle by simply turning a ring on the control section of the scope.	left or right up to 120°	left or right up to 120°
Video connection section		
Scope connector	Water resistant one-touch connector	Water resistant one-touch connector
Configuration of Video connection section and Light guide connector section		
Software		
Correction of pixel defect	Have	Have
Scope information		
Individual scope information (Scope ID)	Have	Have
Compatibility of endotherapy accessories		
High frequency treatment accessories	Not Available	Not Available

Item	Subject Device	Predicate Device
	BF-XP190 (combination with CV-1500)	BF-XP190 (combination with CV-190/CLV-190)
	TBD	K201758
Laser treatment accessories	Not Available	Not Available
Other		
Total weight	840g	840g

Table 3 – BF-XT190

Item	Subject Device	Predicate Device
	BF-XT190 (combination with CV-1500)	BF-XT190 (combination with CV-190/CLV-190)
	TBD	K183419
Regulation Number	874.4680	874.4680
Regulatory Class	Class II	Class II
Product Code	EOQ; Bronchoscope (Flexible Or Rigid)	EOQ; Bronchoscope (Flexible Or Rigid)
Review Panel	Ear Nose and Throat	Ear Nose and Throat
Common name	BRONCHOSCOPE	BRONCHOSCOPE
Manufacturer	OLYMPUS MEDICAL SYSTEMS CORP.	OLYMPUS MEDICAL SYSTEMS CORP.
Indications for Use	The EVIS EXERA III Bronchovideoscopes BF-XT190 are 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-XT190 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.
Use Environment	Healthcare facility/hospital	Healthcare facility/hospital
Single-Use/Reuse	Reusable	Reusable
Duration and type of contact	Surface-contacting device in contact with mucosal membranes. The contact duration is limited exposure (<24 hrs).	Surface-contacting device in contact with mucosal membranes. The contact duration is limited exposure (<24 hrs).

Item	Subject Device	Predicate Device
	BF-XT190 (combination with CV-1500)	BF-XT190 (combination with CV-190/CLV-190)
	TBD	K183419
Depth of Field	2 - 50 mm	2 - 50 mm
Direction of Forward View	0° (Forward viewing)	0° (Forward viewing)
Field of View(FOV)	110°	110°
Distortion		
Magnification of Objective Lens at Optimum Working Distance	0.017	0.017
Pixels per square mm	226,760	226,760
Active Area of CCD Chip	(H)477μm×(V)468μm	(H)477μm×(V)468μm
Total Number of Pixels	50,621	50,621
Size of Pixel	(H)2.1μm×(V)2.1μm	(H)2.1μm×(V)2.1μm
Type of CCD Chip	Color	Color
Narrow Band Image (NBI) observation	Available	Available
Red Dichromatic Imaging (RDI) observation	Available	Not Available
Pre-freeze function	Available	Available
Electronic zoom function	Not Available	Not Available
Electronic shutter function	Not Available	Not Available
Records of endoscope's information	Available	Available
Outer Diameter of Distal End	Φ6.1mm	Φ6.1mm

Item		Subject Device	Predicate Device
		BF-XT190 (combination with CV-1500)	BF-XT190 (combination with CV-190/CLV-190)
		TBD	K183419
Outer Diameter of Insertion Tube		Φ6.3mm	Φ6.3mm
Bending Section Angulation		UP:180°, DOWN:130°	UP:180°, DOWN:130°
Working Length		600mm	600mm
Instrument Channel inner diameter [mm]		φ3.2	φ3.2
Distal end enlarged		 1 Objective lens 2 Light guide lens 3 Instrument channel outlet	 1 Objective lens 2 Light guide lens 3 Instrument channel outlet
Total Length		880mm	880mm
Minimum visible distance		1.5mm	1.5mm
Direction from which EndoTherapy accessories enter and exit the endoscopic image			
Material	Insertion Tube (Outer layer)	Fluoro Resin (F-COAT-KAI)	Fluoro Resin (F-COAT-KAI)
	Bending section rubber	Fluoro Rubber (GR1005)	Fluoro Rubber (GR1005)
	Adhesive on the bending rubber	Epoxy Glue (ES-19MC)	Epoxy Glue (ES-19MC)
	Distal end adhesive	Epoxy Glue (ES-19MC)	Epoxy Glue (ES-19MC)
	Instrument channel	Polytetrafluoro-ethylene	Polytetrafluoro-ethylene
	Distal end	Polysulfone (P1700-216)	Polysulfone (P1700-216)
	Objective lens	Glass (Sapphire)	Glass (Sapphire)
	Light guide lens	Glass (Sapphire)	Glass (Sapphire)

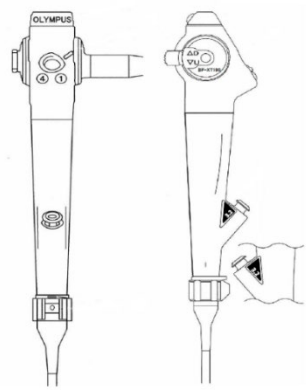
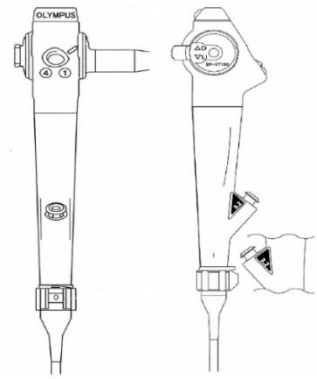
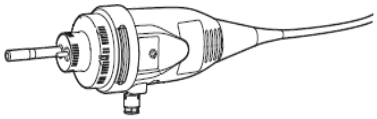
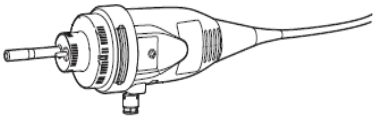
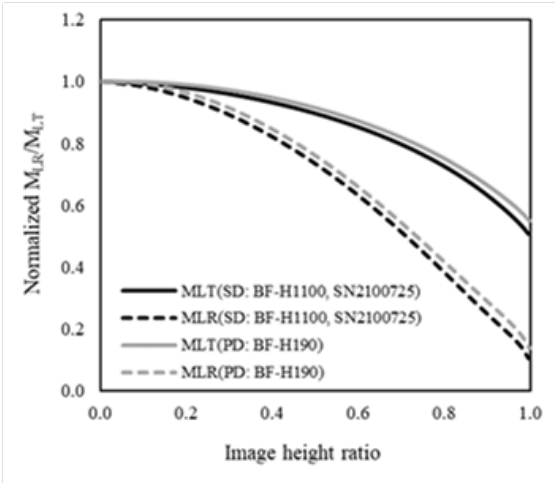
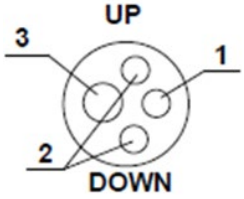
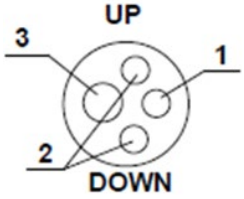
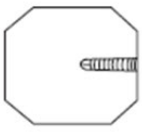
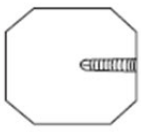
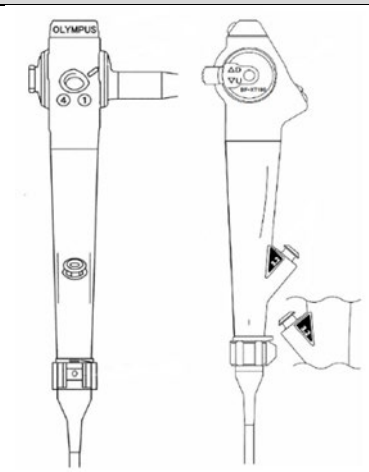
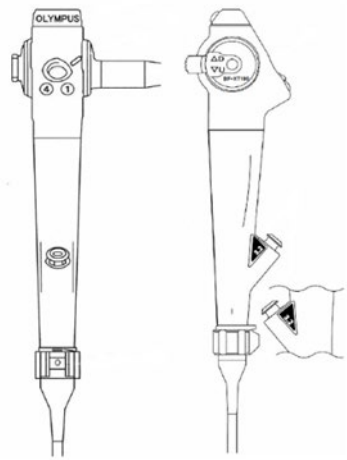
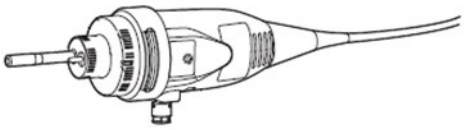
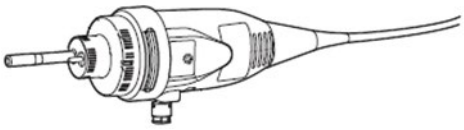
Item	Subject Device	Predicate Device
	BF-XT190 (combination with CV-1500)	**BF-XT190 (combination with CV-190/CLV-190)**
	TBD	**K183419**
Configuration of Control section and location of scope switch		
The insertion tube rotation angle by simply turning a ring on the control section of the scope.	left or right up to 120°	left or right up to 120°
Video connection section		
Scope connector	Water resistant one-touch connector	Water resistant one-touch connector
Configuration of Video connection section and Light guide connector section		
Software		
Correction of pixel defect	Have	Have
Scope information		
Individual scope information (Scope ID)	Have	Have
Compatibility of endotherapy accessories		
High frequency treatment accessories	Available	Available
Laser treatment accessories	Available	Available
Other		
Total weight	840g	840g

Table 4 – BF-H1100

	SUBJECT DEVICE **BF-H1100 Bronchoscope**	**PREDICATE DEVICE** **BF-H1100 Bronchoscope** **(K222861)**
Manufacturer	**OLYMPUS MEDICAL SYSTEMS CORP**	**OLYMPUS MEDICAL SYSTEMS CORP**
Classification & Regulation Number	Class II 21 CFR §874.4680, 21 CFR §874.4760, 21 CFR §876.1500	Class II 21 CFR §874.4680, 21 CFR §874.4760, 21 CFR §876.1500
Product Code	**EOQ:** Bronchoscope (Flexible or rigid) **EOB:** Nasopharyngoscope (Flexible or rigid) **NWB:** endoscope, accessories, narrow band spectrum	**EOQ:** Bronchoscope (Flexible or rigid) **EOB:** Nasopharyngoscope (Flexible or rigid) **NWB:** endoscope, accessories, narrow band spectrum
Indications for Use	The "BRONCHOVIDEOSCOPE OLYMPUS BF-H1100 is intended to be used with an Olympus video system center, 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.	The "BRONCHOVIDEOSCOPE OLYMPUS BF-H1100 is intended to be used with an Olympus video system center, 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	- CCD - CYM color filter Sequential read image signal	- CCD - CYM color filter Sequential read image signal
Number of pixels	465,588	465,588
Pixel size	1.5 µm (H) × 1.5 µm (V)	1.5 µm (H) × 1.5 µm (V)
Optical System		
Direction of View	0°	0°
Field of View	120°	120°
Depth of Field	3 - 100 mm	3 - 100 mm

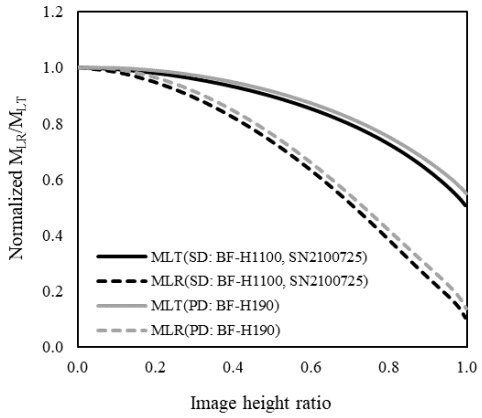
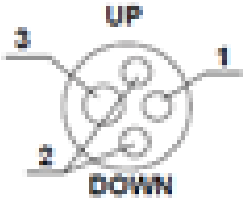
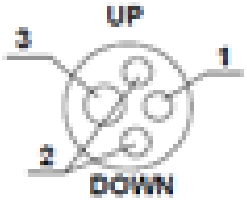
	SUBJECT DEVICE BF-H1100 Bronchoscope	PREDICATE DEVICE BF-H1100 Bronchoscope (K222861)
Distortion		
Insertion Section		
Distal end outer diameter	ø 4.9 mm	ø 4.9 mm
Distal end enlarged	 1 Objective lens 2 Light guide Lens 3 Instrument channel outlet	 1 Objective lens 2 Light guide Lens 3 Instrument channel outlet
Insertion tube outer diameter	ø 4.9 mm	ø 4.9 mm
Insertion section working length	600 mm	600 mm
Instrument Channel		
Channel inner diameter	ø 2.2 mm	ø 2.0 mm
Minimum visible distance	3 mm	3 mm
Direction from which EndoTherapy accessories enter and exit the endoscopic image		

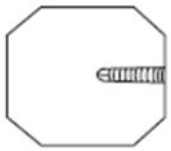
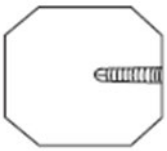
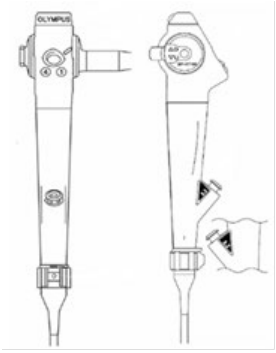
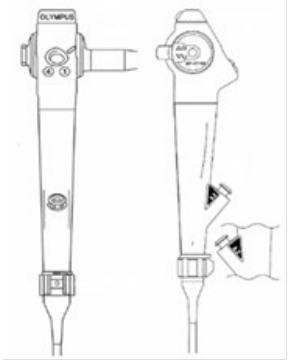
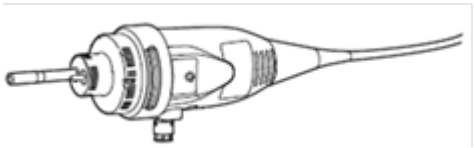
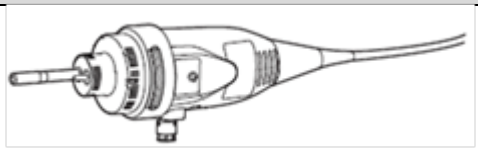
	SUBJECT DEVICE BF-H1100 Bronchoscope	PREDICATE DEVICE BF-H1100 Bronchoscope (K222861)
Configuration		
The insertion tube rotation angle by simply turning a ring on the control section of the scope	left or right up to 120°	left or right up to 120°
Connector Section		
Configuration		
Bending Section		
Angulation range	UP 210° DOWN 130°	UP 210° DOWN 130°
Total Length		
Total length	880 mm	880 mm
Total Weight		
Total Weight	940 g	940 g
Function		
Pre-freeze function	Available	Available
Electronic zoom function	Available	Available
Electronic shutter function	Available	Available
Records of endoscope's information	Available	Available
NBI observation	Available	Available
RDI observation	Available	Available

	SUBJECT DEVICE BF-H1100 Bronchoscope	PREDICATE DEVICE BF-H1100 Bronchoscope (K222861)
High frequency treatment	Available	Available
Laser treatment	Available	Available
Scope ID	Available	Available

Table 5 – BF-1TH1100

	Subject Device BF-1TH1100 Bronchoscope	Predicate Device BF-1TH110 Bronchoscope (K222861)
Manufacturer	**OLYMPUS MEDICAL SYSTEMS CORP**	**OLYMPUS MEDICAL SYSTEMS CORP**
Classification & Regulation Number	Class II 21 CFR §874.4680, 21 CFR §874.4760, 21 CFR §876.1500	Class II 21 CFR §874.4680, 21 CFR §874.4760, 21 CFR §876.1500
Product Code	**EOQ:** Bronchoscope (Flexible or rigid) **EOB:** Nasopharyngoscope (Flexible or rigid) **NWB:** endoscope, accessories, narrow band spectrum	**EOQ:** Bronchoscope (Flexible or rigid) **EOB:** Nasopharyngoscope (Flexible or rigid) **NWB:** endoscope, accessories, narrow band spectrum
Indications for Use	The BRONCHOVIDEOSCOPE OLYMPUS BF-1TH1100 is intended to be used with an Olympus video system center, 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.	The BRONCHOVIDEOSCOPE OLYMPUS BF-1TH1100 is intended to be used with an Olympus video system center, 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.
Image Sensor		
Type	- CCD - CYM color filter - Sequential read image signal	- CCD - CYM color filter - Sequential read image signal
Number of Pixels	465,588	465,588
Pixel Size	1.5 µm (H) × 1.5 µm (V)	1.5 µm (H) × 1.5 µm (V)

	Subject Device **BF-1TH1100 Bronchoscope**	**Predicate Device** **BF-1TH110 Bronchoscope** **(K222861)**
Optical System		
Direction of View	0°	0°
Field of View	120°	120°
Depth of Field	3 - 100 mm	3 - 100 mm
Distortion		
Insertion Section		
Distal end outer diameter	ø 5.8 mm	ø 5.8 mm
Distal end enlarged	 1 Objective lens 2 Light guide lens 3 Instrument channel outlet	 1 Objective lens 2 Light guide lens 3 Instrument channel outlet
Insertion tube outer diameter	ø 6.1 mm	ø 6.1mm
Insertion section working length	600 mm	600 mm
Instrument Channel		
Channel inner diameter	ø 3.0 mm	ø 3.0 mm
Minimum visible distance	3 mm	3 mm

	Subject Device BF-1TH1100 Bronchoscope	Predicate Device BF-1TH110 Bronchoscope (K222861)
Direction from which EndoTherapy accessories enter and exit the endoscopic image		
Control Section		
Configuration		
The insertion tube rotation angle by simply turning a ring on the control section of the scope.	left or right up to 120°	left or right up to 120°
Connector Section		
Configuration		
Bending Section		
Angulation range	UP 180° DOWN 130°	UP: 180° DOWN: 130°
Total Length		
Total length	880 mm	880 mm
Total Weight		
Total weight	950 g	950 g
Function		
Pre-freeze function	Available	Available
Electronic zoom function	Available	Available
Electronic shutter function	Available	Available

	Subject Device **BF-1TH1100 Bronchoscope**	**Predicate Device** **BF-1TH110 Bronchoscope** **(K222861)**
Records of endoscope's information	Available	Available
NBI observation	Available	Available
RDI observation	Available	Available
High frequency treatment	Available	Available
Laser treatment	Available	Available
Scope ID	Available	Available

8. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination for BF-XP190, BF-P190, and BF-XT-190:

1) Performance testing - Bench

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

- Thermal Safety
- Photobiological Safety
- Color Performance
- Resolution
- Noise and Dynamic Range
- Image Intensity Uniformity
- Video Latency
- RDI
- TXI
- BAI-MAC
- Automatic Brightness Adjustment
- Pre-Freeze
- Ignition Factors Safety Study (Laser)*
- Ignition Factors Safety Study (High-Frequency)*
- Ignition Factors Safety Study (APC)*
- Ignition Factors Safety Study (Scope Comparison)*

*Testing is also applicable to BF-H1100 and BF-1TH1100 to address the labeling change

2) Performance testing - Animal

Animal testing was performed to assess the imaging modes of WLI, NBI, TXI, and BAI-MAC with video processor CV-1500.

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
- Shelf Life
- Stability Testing
- Package Integrity Test
- Software Testing and Cybersecurity
- Electrical Safety and EMC
- Residual Toxicity of Reprocessing Chemicals
- Human Factors
- 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-XP190, OLYMPUS BF-P190, and BF-XT190) and BRONCHOVIDEOSCOPE BF-H1100 and BF-1TH1100 raise no new issue of safety and effectiveness and are substantially equivalent to the predicate device in terms of safety, effectiveness, and performance.