June 15, 2023

Olympus Medical Systems Corporation
% Brenda Geary
Manager, Regulatory Affairs
Olympus Corporation of the Americas
800 West Park Drive
Westborough, Massachusetts 01581

Re: K222861
Trade/Device Name: EVIS XI Video System Center Olympus CV-1500, 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, FET, NWB, NTN
Dated: May 16, 2023
Received: May 16, 2023

Dear Brenda Geary:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222861

Device Name
EVIS X1 VIDEO SYSTEM CENTER OLYMPUS CV-1500

Indications for Use *(Describe)*
The EVIS X1 VIDEO SYSTEM CENTER OLYMPUS CV-1500 is intended to be used with Olympus ancillary equipment for endoscopic diagnosis, treatment, and video observation. This product is designed to process electronic signals transmitted from Olympus video endoscopes, output images to monitors, provide illumination to the endoscope, supply air through the endoscope while inside the body and control/monitor ancillary equipment. NBI (Narrow Band Imaging), RDI (Red Dichromatic Imaging), TXI (TeXture and color enhancement Imaging), and BAI-MAC (Brightness Adjustment Imaging with Maintenance of Contrast) are adjunctive tools for endoscopic examination which can be used to supplement Olympus white light imaging. NBI, RDI, TXI and BAI-MAC are not intended to replace histopathological sampling as a means of diagnosis. The CV-1500 Video System Center is compatible with scopes within the EVIS 190 and 1100 families.

Type of Use *(Select one or both, as applicable)*

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222861

Device Name
BRONCHOVIDEOSCOPE OLYMPUS BF-H1100

Indications for Use *(Describe)*
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 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)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222861

Device Name
BRONCHOVIDEOSCOPE OLYMPUS BF-1TH1100

Indications for Use *(Describe)*
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.

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: June 15, 2023

510(k) Summary

SPONSOR INFORMATION

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

Official Correspondent: Brenda Geary
Olympus Corporation of the Americas
800 West Park Drive
Westborough, MA 01581
Cell: (508) 641-0568
Email: brenda.geary@olympus.com

Manufacturing Site(s): *Manufacturer for BF-H1100, BF-1TH1100*
Aizu Olympus Co., Ltd.,
3-1-1 Niiderakita, Aizuwakamatsu-shi, Fukushima 965-8520, Japan

Manufacturer for CV-1500
Shirakawa Olympus Co., Ltd.
3-1 Okamiyama, Odakura, Nishigo-mura, Nishishirakawa-gun, Fukushima 961-8061, Japan

DEVICE IDENTIFICATION

■ **Device Name(s):**	EVIS X1 VIDEO SYSTEM CENTER OLYMPUS CV-1500
■ **Model Name(s):**	OLYMPUS CV-1500
■ **Common Name:**	Endoscopic Video Imaging System
■ **Regulation Number:**	874.4680
■ **Regulation Name:**	Bronchoscope (flexible or rigid) and accessories
■ **Regulatory Class:**	II
■ **Product Code:**	EOQ: Bronchoscope (Flexible or Rigid) FET (Endoscopic Video Imaging System/Component, Gastroenterology-Urology) NWB (endoscope, accessories, narrow band spectrum) NTN (Led Light Source)
■ **Classification Panel:**	Ear Nose & Throat (EOQ, EOB) Gastroenterology/Urology (FET, NWB, NTN)

■ **Device Name(s):**	BRONCHOVIDEOSCOPE OLYMPUS BF-H1100
■ **Model Name(s):**	OLYMPUS BF-H1100
■ **Common Name:**	Bronchoscope
■ **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 & Throat (EOQ, EOB) Gastroenterology/Urology (NWB)

■ **Device Name(s):**	BRONCHOVIDEOSCOPE OLYMPUS BF-1TH1100
■ **Model Name(s):**	OLYMPUS BF-1TH1100
■ **Common Name:**	Bronchoscope
■ **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 & Throat (EOQ, EOB) Gastroenterology/Urology (NWB)

PREDICATE DEVICES

- **Predicate device for CV-1500**

Device Name	510(k) Submitter	510(k) No.
PREDICATE		
VIDEO SYSTEM CENTER OLYMPUS CV-190 & XENON LIGHT SOURCE OLYMPUS CLV-190	Olympus Medical Systems Corp.	K121959, K131780

- **Predicate device for BF-H1100**

Device Name	510(k) Submitter	510(k) No.
PREDICATE		
EVIS EXERA III BRONCHOSCOPE OLYMPUS BF-H190	Olympus Medical Systems Corp..	K121959

- **Predicate device for BF-1TH1100**

Device Name	510(k) Submitter	510(k) No.
PREDICATE		
EVIS EXERA III BRONCHOSCOPE OLYMPUS BF-1TH190	Olympus Medical Systems Corp..	K121959

DEVICE DESCRIPTION

EVIS X1 VIDEO SYSTEM CENTER OLYMPUS CV-1500

The CV-1500 video system center is indicated to process electronic signals transmitted from Olympus video endoscopes, output images to monitors, and be used with Olympus ancillary equipment for endoscopic diagnosis, treatment, and video observation. This product also functions as a pump to supply air through the endoscope, a light source to the endoscope, and a controller/monitor of ancillary equipment. NBI (Narrow Band Imaging), RDI (Red Dichromatic Imaging), TXI (TeXture and color enhancement Imaging), and BAI-MAC (Brightness Adjustment Imaging with Maintenance of Contrast) are adjunctive tools for endoscopic examination which can be used to supplement Olympus white light imaging. NBI, RDI, TXI and BAI-MAC are not intended to replace histopathological sampling as a means of diagnosis.

RDI (Red Dichromatic Imaging) observation:
RDI is optical-digital observation using red dichromatic narrow band light and green illumination light to enhance visibility of bleeding points in the endoscopic image due to the difference in light absorption.

TXI (TeXture and color enhancement Imaging):
TXI emphasizes tonal changes, patterns, and image outlines. It also corrects the brightness of dark areas.

BAI-MAC (Brightness Adjustment Imaging with Maintenance of Contrast):
BAI-MAC maintains the brightness of the bright part of the endoscopic image and corrects the brightness of the dark part of the endoscopic image.

BRONCHOSCOPE OLYMPUS BF-H1100 & BF-1TH1100

The BF-H1100 and BF-1TH1100 endoscopes consist of three parts: the control section, the insertion section, and the connector section. The endoscope receives the illumination light from light guide connector connected to the video system center (CV-1500). The illumination light is transferred to the distal end through the optical fiber bundle inside of the endoscope and illuminates the inside of the patient body through the illumination lens at the distal end.

The endoscope receives the reflected light from the inner lumen of a patient by objective lens at the distal end. The built-in charge-coupled device (CCD) at the distal end converts the light to the electrical signal, and the signal is sent to the video system center via the electrical cable and the video connector of the endoscope. The endoscope transfers the image signal and displays the observation image on the screen.

INDICATIONS FOR USE

EVIS X1 VIDEO SYSTEM CENTER OLYMPUS CV-1500

The EVIS X1 VIDEO SYSTEM CENTER OLYMPUS CV-1500 is intended to be used with Olympus ancillary equipment for endoscopic diagnosis, treatment, and video observation. This product is designed to process electronic signals transmitted from Olympus video endoscopes, output images to monitors, provide illumination to the endoscope, supply air through the endoscope while inside the body and control/monitor ancillary equipment. NBI (Narrow Band Imaging), RDI (Red Dichromatic Imaging), TXI (TeXture and color enhancement Imaging), and BAI-MAC (Brightness Adjustment Imaging with Maintenance of Contrast) are adjunctive tools for endoscopic examination which can be used to supplement Olympus white light imaging. NBI, RDI, TXI and BAI-MAC are not intended to replace histopathological sampling as a means of diagnosis. The CV-1500 Video System Center is compatible with scopes within the EVIS 190 and 1100 families.

BRONCHOSCOPES - OLYMPUS BF-H1100 & BF-1TH1100

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-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.

COMPARISON OF TECHNOLOGY CHARACTERISTICS WITH THE PREDICATE DEVICE

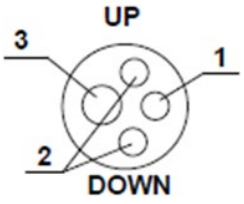
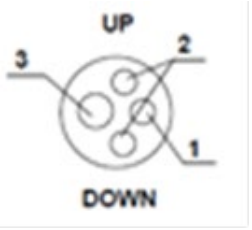
EVIS XI VIDEO SYSTEM CENTER CV-1500

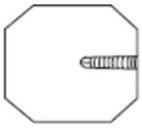
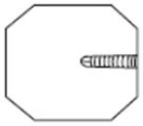
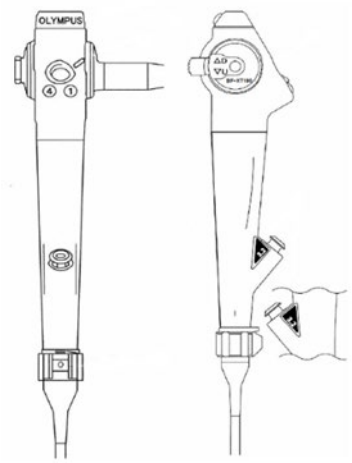
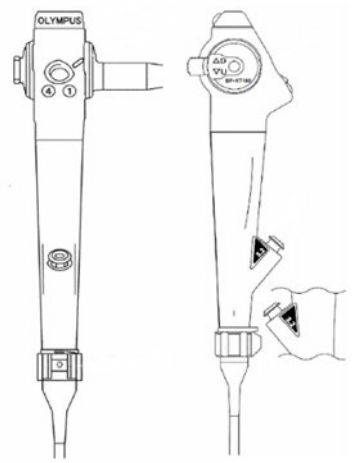
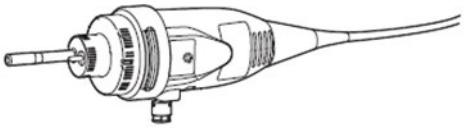
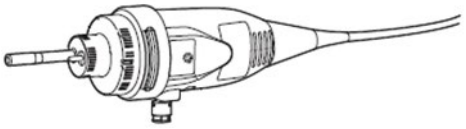
	SUBJECT DEVICE ***CV-1500 Video System Center***	**PREDICATE** ***CV-190 Video System Center & CLV-190 Light Source (K121959, K131780)***
Manufacturer	OLYMPUS MEDICAL SYSTEMS CORP	**SAME**
Classification & Regulation Number	Class II 21 CFR §874.4680	**SAME**
Product Code	**EOQ** - Bronchoscope (Flexible or Rigid) **FET** -endoscopic video imaging system/component, gastroenterology-urology **NWB** - endoscope, accessories, narrow band spectrum **NTN** - led light source	**EOQ -** bronchoscope (flexible or rigid) **EOB** Nasopharyngoscope (Flexible or rigid) **NWB** - endoscope, accessories, narrow band spectrum
Indications for Use	The EVIS X1 VIDEO SYSTEM CENTER OLYMPUS CV-1500 is intended to be used with Olympus ancillary equipment for endoscopic diagnosis, treatment, and video observation. This product is designed to process electronic signals transmitted from Olympus video endoscopes, output images to monitors, provide illumination to the endoscope, supply air through the endoscope while inside the body and control/monitor ancillary equipment. NBI (Narrow Band Imaging), RDI (Red Dichromatic Imaging), TXI (TeXture and color enhancement Imaging), and BAI-MAC (Brightness Adjustment Imaging with Maintenance of Contrast) are adjunctive tools for endoscopic examination which can be used to supplement Olympus white light imaging. NBI, RDI, TXI and BAI-MAC are not intended to replace histopathological sampling as a means of diagnosis.	This video system center is intended to be used with OLYMPUS camera heads, endoscopes, light sources, monitors, EndoTherapy accessories, and other ancillary equipment for endoscopic diagnosis, treatment, and video observation. This light source is intended to be used With Olympus endoscopes, video system center, and other ancillary equipment for endoscopic diagnosis, treatment and video observation.
Overall System Features		
Rated voltage	100 -120V AC ±10 %	**Video Center:** 100 - 120 V AC ± 10% **Light Source:** 100 - 120 V AC ± 10%
Rated frequency	50/60 Hz ± 1 Hz	**Video Center:** 50/60 Hz ± 1 Hz **Light Source:** 50/60 Hz ± 1 Hz
Over-current protection	Fuse type (Built-in type)	**Video Center:** Fuse type (Built-in type) **Light Source:** Fuse type (Built-in type)
Rated input	600 VA	**Video Center:** 150 VA **Light Source:** 600 VA
Dimensions (W×H×D)	370×198×488 mm	**Video Center:** 370×85×455 mm **Light Source:** 370×150×476 mm
Dimensions (maximum) (W×H×D)	398×218×580 mm	**Video Center:** 382×91×489 mm **Light Source:** 382×162×551 mm

	SUBJECT DEVICE *CV-1500 Video System Center*	PREDICATE *CV-190 Video System Center & CLV-190 Light Source (K121959, K131780)*
Weight	19.4 kg	**Video Center:** 10.7 kg **Light Source:** 19 kg
Communication terminals	• Output socket • 1000BASE-T • Foot switch • Keyboard • Adaptor • Recorder • DF • Printer • CV-LINK • LINK OUT • UPD/PSCU	**Video Center:** • Video connector socket • 100BASE-TX • Foot switch • Keyboard • Option 1 • Option 2 • Adapter • Light source • Light source 2 • Remote 1 • Remote 2 • Monitor remote 1 • Monitor remote 2 • EUS • CV-LINK **Light Source:** • Output socket • CV 1 • CV 2 • LINK – OUT • UPD
Touch panel	Provided (Brightness 10 steps)	**Video Center:** Not provided **Light Source:** Not provided
Observation mode	WLI, NBI, RDI	**Video Center:** WLI, NBI **Light Source:** WLI, NBI
Record to portable memory	Provided	**Video Center:** Provided **Light Source:** Not provided
Cooling method of inside	Fan (Variable rotation)	**Video Center:** Fan (Forced-air cooling) **Light Source:** Fan (Variable rotation)
Type of protection against electric shock	Class I	**Video Center:** Class I **Light Source:** Class I
Degree of protection against electric shock of applied part	Type BF applied part (Depends on applied part)	**Video Center:** Type BF or CF applied part (Depends on applied part) **Light Source:** Type BF or CF applied part (Depends on applied part)
Degree or protection against explosion	The video system center should be kept away from flammable gases.	**Video Center:** The video system center should be kept away from flammable gases. **Light Source:** The light source should be kept away from flammable gases.
Light Source Features		
Bulb type	LED	Xenon short-arc lamp (ozone-free) 300W
Providing maximum light intensity	Less than 3.93 W	3.21 W
Observation mode	WLI, NBI, RDI	WLI, NBI
Emergency Lamp	Not provided	Halogen Lamp 12V35W
Brightness adjustment	Automatic (current control, 17 steps)	• Automatic (current control, 17 steps) • Manual (current control, 17 steps)

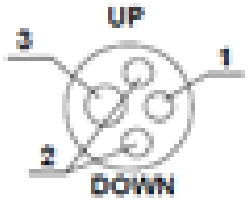
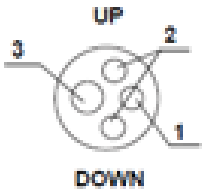
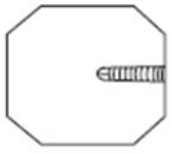
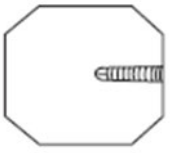
	SUBJECT DEVICE ***CV-1500 Video System Center***	**PREDICATE** ***CV-190 Video System Center & CLV-190 Light Source (K121959, K131780)***
Video Center Features		
Analog signal output	VBS composite	RGB component VBS composite and Y/C; simultaneous outputs possible.
Digital signal output	SDI:2	SDI:2, DVI:1
User settings	The function settings for up to 20 users can be stored.	The function settings for up to 20 users can be stored.
White Balance adjustment	**BF-H190 and BF-1TH190**Automatically adjusted using the white balance switch at the time of connection with the scope with Scope ID **BF-H1100 and BF-1TH1100**Automatically adjusted without pressing white balance switch	Automatically adjusted using the white balance switch at the time of connection with the scope with Scope ID
Standard color chart output	Color bar image	Color bar image or the 50% white screen can be displayed
Color tone adjustment	• Red adjustment ±8 steps • Blue adjustment ±8 steps • Chroma adjustment ±8 steps	• Red adjustment ±8 steps • Blue adjustment ±8 steps • Chroma adjustment ±8 steps
Contrast	Normal / High / Low	Normal / High / Low
Iris	AUTO/PEAK/AVE	AUTO/PEAK/AVE
Image enhancement	Structure enhancement Type A: (8 steps) Type B: (8 steps) *User can preset three image enhancement settings	Structure enhancement Type A: (8 steps) Type B: (8 steps) Edge enhancement (8 steps) *User can preset three image enhancement settings
TXI modes	Mode 1/Mode 2/Mode 3	Not provided
Image size selection	The size of the endoscopic image can be selected from 2 modes. (Except SDTV)	The size of the endoscopic image can be selected from 2 modes. (Except SDTV)
Electric zoom	Switch between mode 1, mode 2, and mode 3.	Switch between mode 1, mode 2, and mode 3.
PIP/POP	Provided	Provided
Aspect ratio	Switch between 16:9 and 4:3. (Except SDTV)	Switch between 16:9 and 4:3. (Except SDTV)
Freeze	Still the endoscopic image	Still the endoscopic image
Pre-freeze	Available	Available
Custom switch	Assign specific functions to the following buttons. • Remote switches (Up to 5) • Foot switches (Up to 2) • Keyboard custom key (Up to 4) • Touch panel custom button of basic functions screen (Up to 3) • Touch panel custom button of custom functions screen (Up to 10)	Assign specific functions to the following buttons. • Remote switches (Up to 5) • Foot switches (Up to 2) • Keyboard custom key (Up to 4)

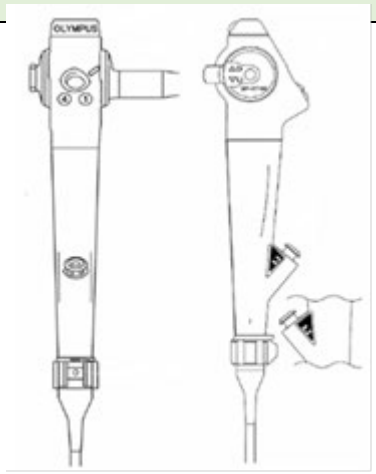
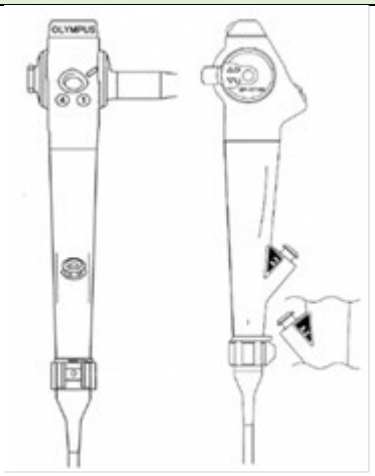
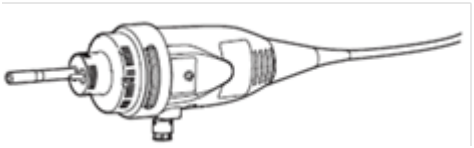
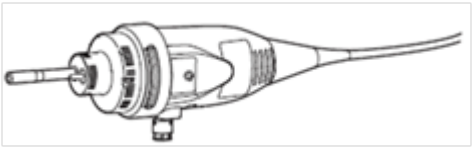
Bronchoscope BF-H1100

	SUBJECT DEVICE *BF-H1100 Bronchoscope*	PREDICATE *BF-H190 Bronchoscope* *(K121959)*
Manufacturer	**OLYMPUS MEDICAL SYSTEMS CORP**	**SAME**
Classification & Regulation Number	Class II 21 CFR §874.4680,	**SAME**
Product Code	**EOQ:** Bronchoscope (Flexible or rigid) **NWB:** endoscope, accessories, narrow band spectrum	**SAME**
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.	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	- CCD - CYM color filter Sequential read image signal	- CCD - CYM color filter Sequential read image signal
Direction of View	0°	0°
Field of View	120°	120°
Depth of Field	3 - 100 mm	3 - 100 mm
Distal end outer diameter	ø 4.9 mm	ø 5.5mm
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 5.1 mm
Insertion section working length	600 mm	600 mm
Channel inner diameter	ø 2.2 mm	ø 2.0 mm
Channel length	850 mm	850 mm
Total length	880 mm	880 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 *BF-H190 Bronchoscope* *(K121959)*
		
Configuration		
Configuration		
Angulation range	UP 210° DOWN 130°	UP 210° DOWN 130°
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 (when using CV-1500)	Available (when using CV-1500)
High frequency treatment	Available	Available
Laser treatment	Available	Available

Bronchoscope BF-1TH1100

	SUBJECT DEVICE: ***BF-1TH1100 Bronchoscope***	**PREDICATE:** ***BF-1TH190 Bronchoscope*** ***(K121959)***
Manufacturer	**OLYMPUS MEDICAL SYSTEMS CORP**	**SAME**
Classification & Regulation Number	Class II 21 CFR §874.4680,	**SAME**
Product Code	**EOQ:** Bronchoscope (Flexible or rigid) **NWB:** endoscope, accessories, narrow band spectrum	**SAME**
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.	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.
Direction of View	0°	0°
Field of View	120°	120°
Depth of Field	3 - 100 mm	3 - 100 mm
Distal end outer diameter	ø 5.8 mm	ø 6.2 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 6.0mm
Insertion section working length	600 mm	600 mm
Channel inner diameter	ø 3.0 mm	ø 2.8 mm
Channel length	850 mm	850 mm
Total length	880 mm	880 mm
Minimum visible distance	3 mm	3 mm
Direction from which EndoTherapy accessories enter and exit the endoscopic image		
Configuration		

	SUBJECT DEVICE: ***BF-1TH1100 Bronchoscope***	**PREDICATE:** ***BF-1TH190 Bronchoscope*** ***(K121959)***
		
Configuration		
Angulation range	UP 180° DOWN 130°	UP: 180° DOWN: 130°
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 (when using CV-1500)	Available (when using CV-1500)
High frequency treatment	Available	Available
Laser treatment	Available	Available

PERFORMANCE DATA

- **Software verification and validation**

  Software verification and validation testing were conducted for the CV-1500, BF-H1100 and BF-1TH1100 devices and documentations were provided as recommended by FDA's Guidance for Industry and FDA Staff, *"Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices"* and *"Content of Premarket Submissions for Management of Cybersecurity in Medical Devices"*.

- **Electrical safety and electromagnetic compatibility (EMC)**

  Electrical safety and EMC testing were conducted for the CV-1500, BF-H1100 and BF-1TH1100 devices in accordance with the ANSI/AAMI ES 60601-1:2005/(R)2012 and A1:2012 and IEC 60601-2-18:2009 standards for safety and the IEC 60601-1-2:2014 standards for EMC.

- **Performance testing - Bench**

  Bench testing as listed below were conducted for CV-1500, BF-H1100, and BF-1TH1100 to ensure that the subject device performs as intended and meet design specifications.

  - Thermal Safety
  - Durability
  - Photobiological Safety
  - Color Performance
  - Direction of View
  - Field of View
  - Distortion
  - Resolution
  - Depth of Field
  - Noise and Dynamic Range
  - Image Intensity Uniformity
  - Video Latency
  - RDI
  - TXI and BAI-MAC
  - Automatic Brightness Adjustment
  - Pre-Freeze

- **Performance testing - Animal**

  An animal study was performed for CV-1500 to confirm the White Light Imaging (WLI) and Narrow Band Imaging (NBI) performance, TeXture and color enhancement Imaging (TXI) and Brightness Adjustment Imaging with MAintenance of Contrast (BAI-MAC).

- **Performance testing - Clinical**

  No clinical study was performed to demonstrate substantial equivalence.

- **Risk management**

  Risk management was performed for the CV-1500, BF-H1100 and BF-1TH1100 devices in accordance with ISO 14971:2007. The design verification tests and the acceptance criteria were identified and performed as a result of the risk management.

CONCLUSION

Based on the indications for use, technological characteristics, performance testing and technological comparison to the predicate device, the CV-1500, BF-H1100 and BF-1TH1100 devices raise no new issues of safety and effectiveness and are substantially equivalent to the predicate devices in terms of safety, effectiveness and performance.