May 15, 2025

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

Re: K250432
Trade/Device Name: Colonovideoscope (CF-EZ1500DL); Colonovideoscope (CF-EZ1500DI); Gastrointestinal Videoscope (GIF-EZ1500)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: FDF, FDS, NWB
Dated: February 14, 2025
Received: February 14, 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,

Shanil P. Haugen -S

Shanil P. Haugen, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal, Obesity and Transplant Devices
OHT3: Office of Gastrorenal, ObGyn, General Hospital, and Urology 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.

Submission Number *(if known)*

K250432

Device Name

Colonovideoscope (CF-EZ1500DL); Colonovideoscope (CF-EZ1500DI); Gastrointestinal Videoscope (GIF-EZ1500)

Indications for Use *(Describe)*

The COLONOVIDEOSCOPE OLYMPUS CF-EZ1500DL & CF-EZ1500DI are intended to be used with a video system center, endoscope position detecting unit, documentation equipment, monitor, endoscopic therapy accessories (such as a biopsy forceps), and other ancillary equipment for endoscopy and endoscopic surgery.

The COLONOVIDEOSCOPE OLYMPUS CF-EZ1500DL/I are indicated for use within the lower digestive tract (including the anus, rectum, sigmoid colon, colon, and ileocecal valve).

The GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-EZ1500 is intended to be used with a video system center, documentation equipment, monitor, endoscopic therapy accessories (such as a biopsy forceps), and other ancillary equipment for endoscopy and endoscopic surgery.

The GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-EZ1500 is indicated for use within the upper digestive tract (including the esophagus, stomach, and duodenum).

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.

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Date Prepared: 04/11/2025

510(k) Summary

CONTACT DETAILS

■ 510(k) Submitter: OLYMPUS MEDICAL SYSTEMS CORP.
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• Manufacturing site: Aizu Olympus Co., Ltd.
3-1-1 Niiderakita, Aizuwakamatsu-shi, Fukushima 965-8520, Japan

DEVICE NAME

Device Trade Name	OLYMPUS CF-EZ1500DL
Common Name	Colonovideoscope
Regulation Number	876.1500
Classification Name	Endoscope and accessories
Regulatory Class	II
Product Code	FDF, NWB

Device Trade Name	OLYMPUS CF-EZ1500DI
Common Name	Colonovideoscope
Regulation Number	876.1500
Classification Name	Endoscope and accessories
Regulatory Class	II
Product Code	FDF, NWB

Device Trade Name	OLYMPUS GIF-EZ1500
Common Name	Gastrointestinal Videoscope
Regulation Number	876.1500
Classification Name	Endoscope and accessories
Regulatory Class	II
Product Code	FDS, NWB

LEGALLY MARKETED PREDICATE DEVICE

Device Name	510(k) Submitter	510(k) No.	Product Code
Colonovideoscope Olympus CF-HQ1100L/I	Olympus Medical	K222584	FDF
Gastrointestinal Videoscope OLYMPUS GIF-1100	Olympus Medical	K222584	FDS

DEVICE DESCRIPTION SUMMARY

- **General Description of the subject device**

  The COLONOVIDEOSCOPE OLYMPUS CF-EZ1500DL & CF-EZ1500DI is intended to be used with a video system center, Endoscope position detecting unit, documentation equipment, monitor, endoscopic therapy accessories (such as a biopsy forceps), and other ancillary equipment for endoscopy and endoscopic surgery.

  The Olympus COLONOVIDEOSCOPE CF-EZ1500DL/I is indicated for use within the lower digestive tract (including the anus, rectum, sigmoid colon, colon, and ileocecal valve).
  The GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-EZ1500 is intended to be used with a video system center, documentation equipment, monitor, endoscopic therapy accessories (such as a biopsy forceps), and other ancillary equipment for endoscopy and endoscopic surgery.

  Note: The only differences between CF-EZ1500DL and CF-EZ1500DI are the insertion section working length of each scope and the total length of each scope.

  The Olympus GASTROINTESTINAL VIDEOSCOPE GIF-EZ1500 is indicated for use within the upper digestive tract (including the esophagus, stomach, and duodenum).

- **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 innovative 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.

INTENDED USE/INDICATIONS FOR USE

The COLONOVIDEOSCOPE OLYMPUS CF-EZ1500DL & CF-EZ1500DI are intended to be used with a video system center, endoscope position detecting unit, documentation equipment, monitor, endoscopic therapy accessories (such as a biopsy forceps), and other ancillary equipment for endoscopy and endoscopic surgery.

The COLONOVIDEOSCOPE OLYMPUS CF-EZ1500DL/I are indicated for use within the lower digestive tract (including the anus, rectum, sigmoid colon, colon, and ileocecal valve).

The GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-EZ1500 is intended to be used with a video system center, documentation equipment, monitor, endoscopic therapy accessories (such as a biopsy forceps), and other ancillary equipment for endoscopy and endoscopic surgery.

The GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-EZ1500 is indicated for use within the upper digestive tract (including the esophagus, stomach, and duodenum.

INDICATIONS FOR USE COMPARISON

CF-EZ1500DL/I have the same intended use and indications for use as compared to the predicate device. The subject device is also equivalent to the predicate device for direction of view, field of view, geometric distortion, diameters of insertion section, diameters of instrument channel, same control section, configuration of control section and connector section, bending section angulation range, total length, functions (excluding electronic shutter function), Scope ID, and RFID. The subject device also utilizes the same manufacturing materials, and the same methods of reprocessing.

GIF-EZ1500 is has the same intended use and indications for use as the predicate devices. The subject device also is equivalent to the predicate devices for direction of view, field of view, geometric distortion, distal end feature, insertion section working length, instrument channel diameters, configuration of control section and connector section, bending section of angulation range, total length, functions (excluding electronic shutter function and focus switching function), Scope ID, and RFID. The subject device also utilizes the same manufacturing materials, and the same methods of reprocessing.

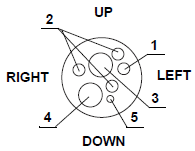
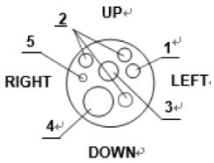
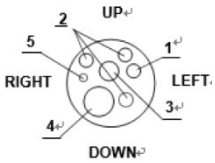
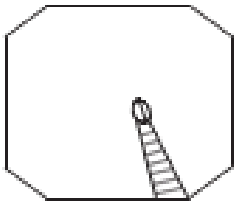
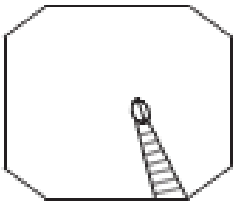
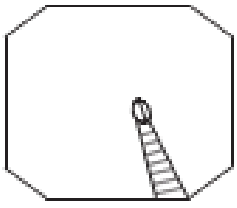
TECHNOLOGICAL COMPARISON

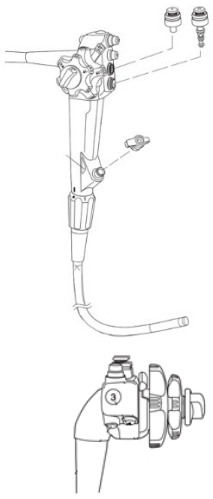
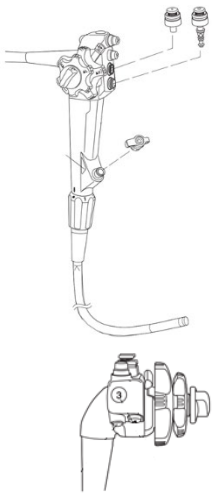
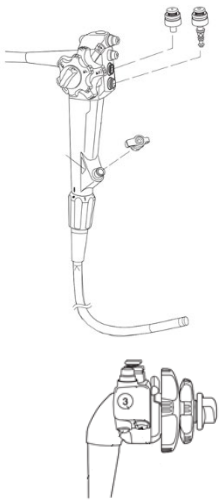
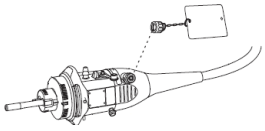
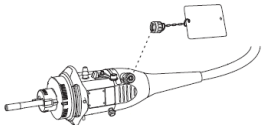
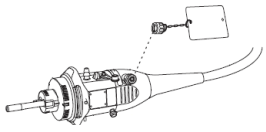
CF-EZ1500DL/I differs from the predicate device for image sensor type and number of pixels, depth of field, and airflow rate. CF-EZ1500DL/I also does not include an electronic shutter function where the predicate does include it.

GIF-EZ1500 differs from the predicate devices for image sensor type, number of pixels, and pixel size, depth of field, outer diameters of distal end, insertion section, insertion tube, and airflow rate. The subject device does not include electronic shutter function where the predicate device does include it. The subject device has a focus switching function, whereas the predicate device does not.

	Subject Device CF-EZ1500DL/I	**Predicate Device CF-HQ1100L/I (K222584)**	**Reference Device CF-HQ190L (K131780)**
510(k) number	This submission	K222584	K131780
Regulation number	876.1500	876.1500	876.1500
Regulatory class	Class II	Class II	Class II
Product code	FDF (colonoscope and accessories, flexible/rigid) NWB (endoscope, accessories, narrow band spectrum)	FDF (colonoscope and accessories, flexible/rigid) NWB (endoscope, accessories, narrow band spectrum)	FDF (colonoscope and accessories, flexible/rigid) NWB (endoscope, accessories, narrow band spectrum)
Classification panel	Gastroenterology and urology	Gastroenterology and urology	Gastroenterology and urology
Common name	COLONOVIDEOSCOPE	COLONOVIDEOSCOPE	COLONOVIDEOSCOPE
Manufacturer	OLYMPUS MEDICAL SYSTEMS CORP.	OLYMPUS MEDICAL SYSTEMS CORP.	OLYMPUS MEDICAL SYSTEMS CORP.
Indications for use	The COLONOVIDEOSCOPE OLYMPUS CF-EZ1500DL & CF-EZ1500DI is intended to be used with a video system center, Endoscope position detecting unit, documentation equipment, monitor, endoscopic therapy accessories (such as a biopsy forceps), and other ancillary equipment for endoscopy and endoscopic surgery.	This instrument is intended to be used with an Olympus video system center, Endoscope position detecting unit, documentation equipment, monitor, EndoTherapy accessories (such as a biopsy forceps), and other ancillary equipment for endoscopy and endoscopic surgery. The Olympus	This instrument is intended to be used with an Olympus video system center, endoscope position detecting unit, light source, documentation equipment, monitor, EndoTherapy accessories (such as a biopsy forceps), and other ancillary equipment for endoscopy and endoscopic surgery. The EVIS EXERA III

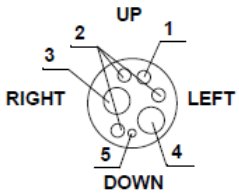
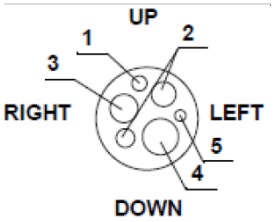
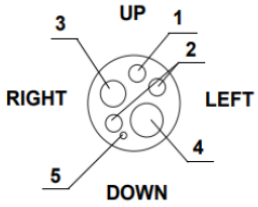
	Subject Device **CF-EZ1500DL/I**	**Predicate Device** **CF-HQ1100L/I (K222584)**	**Reference Device** **CF-HQ190L (K131780)**
	The Olympus COLONOVIDEOSCOPE CF-EZ1500DL/I is indicated for use within the lower digestive tract (including the anus, rectum, sigmoid colon, colon, and ileocecal valve).	COLONOVIDEOSCOPE CF-HQ1100DL/I is indicated for use within the lower digestive tract (including the anus, rectum, sigmoid colon, colon, and ileocecal valve).	COLONOVIDEOSCOPE CF-HQ190L/I is indicated for use within the lower digestive tract (including the anus, rectum, sigmoid colon, colon, and ileocecal valve).
Type	- CMOS - RGB color filter - Sequential read image signal	- CCD - CYM color filter - Sequential read image signal	- CCD - CYM color filter - Sequential read image signal
Direction of View	0°	0°	0°
Field of View	Normal focus mode: 170° Near focus mode: 160°	Normal focus mode: 170° Near focus mode: 160°	Normal focus mode: 170° Near focus mode: 160°
Depth of Field	Normal focus mode: WLI, NBI: 3 - 100 mm RDI: 7 - 100 mm Near focus mode: WLI, NBI: 1.5 - 5.5 mm RDI: 2.5 - 5.5 mm	Normal focus mode: WLI, NBI, RDI: 5 - 100 mm Near focus mode: WLI, NBI, RDI: 2 - 6 mm	Normal focus mode: WLI, NBI, RDI: 5 - 100 mm Near focus mode: WLI, NBI, RDI: 2 - 6 mm *RDI is available only connected to CV-1500
Magnification	× 90 (OEV321UH) × 75 (OEV262H)	× 75 (OEV321UH) × 60 (OEV262H)	× 75 (OEV321UH) × 60 (OEV262H)
Distal end outer diameter	ø 13.2 mm	ø 13.2 mm	ø 13.2 mm
Maximum insertion section outer diameter	ø 14.9 mm	ø 14.9 mm	ø 14.9 mm

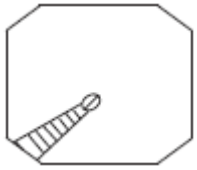
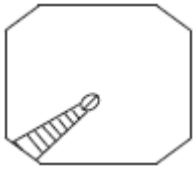
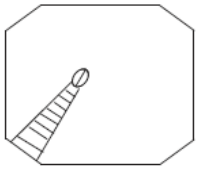
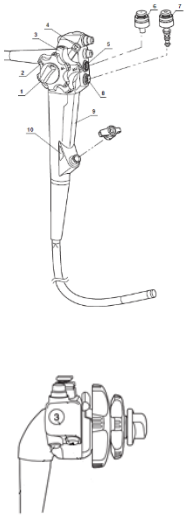
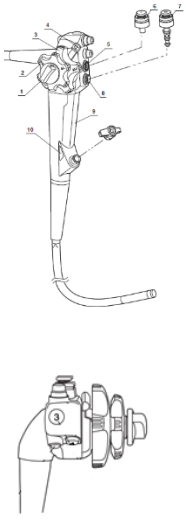
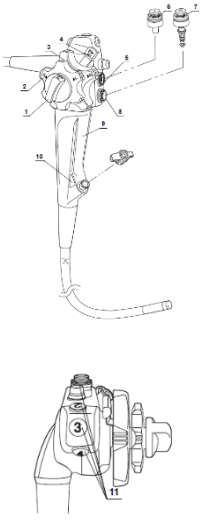
	Subject Device CF-EZ1500DL/I	Predicate Device CF-HQ1100L/I (K222584)	Reference Device CF-HQ190L (K131780)
Distal end enlarged	 1 Air/water nozzle 2 Light guide lens 3 Objective lens 4 Instrument channel outlet 5 Auxiliary water channel	 1 Air/water nozzle 2 Light guide lens 3 Objective lens 4 Instrument channel outlet 5 Auxiliary water channel	 1 Air/water nozzle 2 Light guide lens 3 Objective lens 4 Instrument channel outlet 5 Auxiliary water channel
Insertion tube outer diameter	ø 12.8 mm	ø 12.8 mm	ø 12.8 mm
Insertion section working length	L: 1680 mm I: 1330 mm	L: 1680 mm I: 1330 mm	L: 1680 mm I: 1330 mm
Range of the flexibility adjustment	The rigidity in the most rigid condition is about twice that in the most flexible condition.	The rigidity in the most rigid condition is about twice that in the most flexible condition.	The rigidity in the most rigid condition is about twice that in the most flexible condition.
Channel inner diameter	ø 3.7 mm	ø 3.7 mm	ø 3.7 mm
Minimum channel inner diameter	ø 3.7 mm	ø 3.7 mm	ø 3.7 mm
Minimum visible distance	4 mm (Normal focus mode)	4 mm (Normal focus mode)	4 mm (Normal focus mode)
Direction from which EndoTherapy accessories enter and exit the endoscopic image			

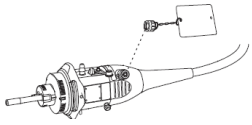
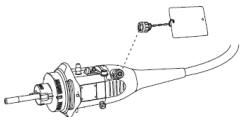
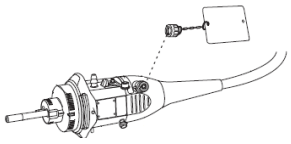
	Subject Device CF-EZ1500DL/I	Predicate Device CF-HQ1100L/I (K222584)	Reference Device CF-HQ190L (K131780)
Configuration			
Configuration			
Airflow rate *At the setting of the air pressure as "high."	30 cm^3/s	25 cm^3/s	25 cm^3/s
Angulation range	UP 180° DOWN 180° RIGHT 160° LEFT 160°	UP 180° DOWN 180° RIGHT 160° LEFT 160°	UP 180° DOWN 180° RIGHT 160° LEFT 160°
Total length			
Total length	L: 2005 mm I: 1655mm	L: 2005 mm I: 1655mm	L: 2005 mm I: 1655mm
Pre-freeze function	Available	Available	Available
Electronic zoom function	Available	Available	Available
Electronic shutter function	Not Available	Available	Available

	Subject Device CF-EZ1500DL/I	Predicate Device CF-HQ1100L/I (K222584)	Reference Device CF-HQ190L (K131780)
Records of endoscope's information	Available	Available	Available
NBI observation	Available	Available	Available
RDI observation	Available	Available	Not Available *RDI is available only connected to CV-1500
High frequency cauterization treatment	Available	Available	Available
Endoscope position detecting function	Available	Available	Available
Passive bending function	Available	Available	Available
Flexibility adjustment function	Available	Available	Available
Zoom function	Not Available	Not Available	Not Available
Focus switching function	Available	Available	Available
Auxiliary water feeding function	Available	Available	Available
Transnasal insertion	Not Available	Not Available	Not Available

	Subject Device **GIF-EZ1500**	**Predicate Device** **GIF-1100 (K222584)**	**Reference Device** **GIF-1TH190 (K232997)**
510(k) number	This submission	K222584	K232997
Regulation number	876.1500	876.1500	876.1500
Regulatory class	Class II	Class II	Class II
Product code	FDS (gastroscope and accessories, flexible/rigid) NWB (endoscope, accessories, narrow band spectrum)	FDS (gastroscope and accessories, flexible/rigid) NWB (endoscope, accessories, narrow band spectrum)	FDS (gastroscope and accessories, flexible/rigid) NWB (endoscope, accessories, narrow band spectrum)
Classification panel	Gastroenterology and urology	Gastroenterology and urology	Gastroenterology and urology
Common name	GASTROINTESTINAL VIDEOSCOPE	GASTROINTESTINAL VIDEOSCOPE	GASTROINTESTINAL VIDEOSCOPE
Manufacturer	OLYMPUS MEDICAL SYSTEMS CORP.	OLYMPUS MEDICAL SYSTEMS CORP.	OLYMPUS MEDICAL SYSTEMS CORP.
Indications for use	The GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-EZ1500 is intended to be used with a video system center, documentation equipment, monitor, endoscopic therapy accessories (such as a biopsy forceps), and other ancillary equipment for endoscopy and endoscopic surgery. The Olympus GASTROINTESTINAL VIDEOSCOPE GIF-EZ1500 is indicated for use within the upper digestive tract (including the esophagus, stomach, and duodenum).	This instrument 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. The Olympus GASTROINTESTINAL VIDEOSCOPE GIF-1100 is indicated for use within the upper digestive tract (including the esophagus, stomach, and duodenum).	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. The EVIS EXERA III GASTROINTESTINAL VIDEOSCOPE GIF-1TH190 is indicated for use within the upper digestive tract (including the esophagus, stomach, and duodenum).

	Subject Device GIF-EZ1500	Predicate Device GIF-1100 (K222584)	Reference Device GIF-1TH190 (K232997)
Type	- CMOS - RGB color filter - Sequential read image signal	- CCD - CYM color filter - Sequential read image signal	- CCD - CYM color filter - Sequential read image signal
Direction of View	0°	0°	0°
Field of View	Normal focus mode: 140° Near focus mode: 140°	140°	140°
Depth of Field	Normal focus mode: WLI, NBI: 3 - 100 mm RDI: 7 - 100 mm Near focus mode: WLI, NBI: 1.5 - 5.5 mm RDI: 2.5 - 5.5 mm	WLI, NBI, RDI: 2 - 100 mm	WLI, NBI: 2 - 100 mm
Magnification	× 100 (OEV321UH) × 85 (OEV262H)	× 70(OEV321UH) × 55(OEV262H)	× 65(OEV321UH) × 55(OEV262H)
Distal end enlarged	 1 Air/water nozzle 2 Light guide lens 3 Objective lens 4 Instrument channel outlet 5 Auxiliary water channel	 1 Air/water nozzle 2 Light guide lens 3 Objective lens 4 Instrument channel outlet 5 Auxiliary water channel	 1 Air/water nozzle 2 Light guide lens 3 Objective lens 4 Instrument channel outlet 5 Auxiliary water channel
Distal end outer diameter	ø 9.9 mm	ø 8.9 mm	ø 10.0mm
Maximum insertion section outer diameter	ø 12.5mm	ø 10.7mm	ø 13.0mm

	Subject Device GIF-EZ1500	Predicate Device GIF-1100 (K222584)	Reference Device GIF-1TH190 (K232997)
Insertion tube outer diameter	ø 9.6 mm	ø 8.9 mm	ø 10.9mm
Insertion section working length	1030 mm	1030 mm	1030 mm
Channel inner diameter	ø 2.8 mm	ø 2.8 mm	ø 3.7 mm
Minimum visible distance	3 mm	3 mm	3 mm
Direction from which EndoTherapy accessories enter and exit the endoscopic image			
Configuration			

	Subject Device **GIF-EZ1500**	**Predicate Device** **GIF-1100 (K222584)**	**Reference Device** **GIF-1TH190 (K232997)**
Configuration			
Airflow rate *At the setting of the air pressure as "high."	30 cm^3/s	25 cm^3/s	25 cm^3/s
Angulation range	UP 210° DOWN 90° RIGHT 100° LEFT 100°	UP 210° DOWN 90° RIGHT 100° LEFT 100°	UP: 210° DOWN: 90° RIGHT:100° LEFT:100°
Total length	1350 mm	1350 mm	1350 mm
Pre-freeze function	Available	Available	Available
Electronic zoom function	Available	Available	Available
Electronic shutter function	Not Available	Available	Available
Records of endoscope's information	Available	Available	Available
NBI observation	Available	Available	Available
RDI observation	Available	Available	Not available
High frequency cauterization treatment	Available	Available	Available
Endoscope position detecting function	Not available	Not available	Not available

	Subject Device GIF-EZ1500	Predicate Device GIF-1100 (K222584)	Reference Device GIF-1TH190 (K232997)
Passive bending function	Not available	Not available	Not available
Flexibility adjustment function	Not available	Not available	Not available
Zoom function	Not Available	Not Available	Not Available
Focus switching function	Available	Not available	Not available
Auxiliary water feeding function	Available	Available	Available
Transnasal insertion	Not available	Not available	Not available

NON-CLINICAL AND/OR CLINICAL TESTS SUMMARY & CONCLUSIONS

Reprocessing validation testing

Reprocessing instruction and reprocessing method validation testing were conducted and documentation were provided as recommended by Guidance for Industry and Food and Drug Administration Staff, "Reprocessing Medical Devices in Health Care Setting: Validation Methods and Labeling".

Biocompatibility testing

Biocompatibility testing were conducted in accordance with the FDA's Guidance for Industry and Food and Drug Administration Staff, Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". The biocompatibility testing included the following tests:

- Cytotoxicity Study Using the Colony Assay
- Intracutaneous Study in Rabbits
- Guinea Pig Maximization Sensitization Test

Software verification and validation

Software verification and validation testing were conducted, 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 was conducted in accordance with the ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021] and IEC 60601-2-18:2009 standards for safety and IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION for EMC.

Performance testing – Bench

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

Durability
Thermal Safety
Photobiological Safety
Transportation
Color Performance
DOF/FOV
Distortion
Resolution
DOF
Noise and Dynamic Range
Image Intensity Uniformity
Video Latency
Rates of Air, Water, and Suction
Magnification
Automatic brightness adjustment
Pre-freeze
Functional Validation
Stability of EDOF Structure
Human Factors Evaluation

Performance testing - Animal

Animal study was performed to confirm the White Light Imaging (WLI) and Narrow Band Imaging (NBI) performance, and the effectiveness of Red Dichromatic Imaging (RDI) and TeXture and color enhancement Imaging (TXI).

Performance testing - Clinical

No clinical study was performed to demonstrate substantial equivalence.

Risk management

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

All testing demonstrated that the subject devices met design specifications, performed as intended, and was equivalent to the subject and reference devices.