June 19, 2024

Olympus Medical Systems Corporation
% Darlene Hull
Regulatory Program Manager
Olympus Corporation of the Americas
800 West Park Drive
Westborough, Massachusetts 01581

Re: K232997
Trade/Device Name: EVIS EXERA III Gastrointestinal Videoscope GIF-1TH190
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: FDS, NWB
Dated: May 17, 2024
Received: May 17, 2024

Dear Darlene Hull:

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.

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, PhD
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K232997

Device Name
EVIS EXERA III Gastrointestinal Videoscope GIF-1TH190

Indications for Use *(Describe)*

This instrument is intended to be used with an Olympus video system center, light source, documentation equipment, monitor, EndoTherapy accessories (such as a biopsy forceps), and other ancillary equipment for endoscopy and endoscopic surgery.

The EVIS EXERA III GASTROINTESTINAL VIDEOSCOPE GIF-1TH190 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.

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Section 5

510(k) Summary

Date Prepared: 09/22/2023

510(k) Summary

1. GENERAL INFORMATION

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

■ Contact Person: Darlene Hull
Olympus Corporation of the Americas
3500 Corporate Parkway PO Box 610
Center Valley, PA 18034-0610, USA
Phone: +1(801) 698-1653
Email: Darlene.hull@olympus.com

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

2. DEVICE IDENTIFICATION

■ Device Name: EVIS EXERA III GASTROINTESTINAL VIDEOSCOPE GIF-1TH190

■ Model Name: GIF-1TH190

■ Common Name: GASTROINTESTINAL VIDEOSCOPE

■ Regulation Number: 21 CFR §876.1500

■ Regulation Name: Endoscope and accessories

■ Regulatory Class: Class II

■ Product Code: FDS, NWB

■ Classification Panel: Gastroenterology/Urology

3. PREDICATE DEVICE

■ **Predicate device**

Device name	510(k) Submitter	510(k) No.
EVIS EXERA III VIDEO SYSTEM ENDOSCOPIC VIDEO IMAGING SYSTEM	OLYMPUS MEDICAL SYSTEMS CORP.	K112680

■ **Reference device**

Device name	510(k) Submitter	510(k) No.
PENTAX Video Upper G.I. Scopes (EG-3490K)	PENTAX Medical Company	K131902

4. DEVICE DESCRIPTION

■ **General Description of the subject device**

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).

■ **Principle of Operation**

The GIF-1TH190 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 GIF-1TH190 is identical to that of the primary predicate device (K112680) and reference device (K131902).

1. **The 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 within the upper digestive tract (including the esophagus, stomach, and duodenum).

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. The Insertion Section

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

3. The Connector Section

The connector section connects the endoscope with the light source (CLV-190) through the universal cord.

■ **List of device components**

The GIF-1TH190 will be packed and offered components listed in the Table below. These devices can be used with commercially available Olympus devices as described within the Instruction Manual.

Model No.	Device Name
MAJ-855	Auxiliary water tube

MH-946	Injection tube
MH-856	Suction cleaning adapter
MH-948	AW channel cleaning adapter
MB-156	ETO cap
MH-944	Channel plug
MB-142	Mouthpiece
BW-412T	Single-use combination cleaning brush

5. INDICATIONS FOR USE

This instrument is intended to be used with an Olympus video system center, light source, documentation equipment, monitor, EndoTherapy accessories (such as a biopsy forceps), and other ancillary equipment for endoscopy and endoscopic surgery.

The EVIS EXERA III GASTROINTESTINAL VIDEOSCOPE GIF-1TH190 is indicated for use within the upper digestive tract (including the esophagus, stomach, and duodenum).

6. COMPARISON OF TECHNOLOGY CHARACTERISTICS WITH THE PREDICATE DEIVCE

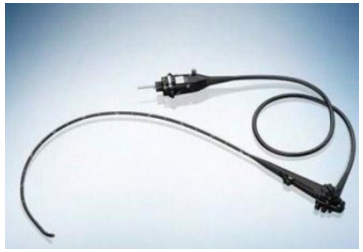
The subject device has the same technological characteristics and design as the predicate device except for the following features:

- Outer Diameter of the Insertion Section
- Inner Diameter of the Instrument Channel
- Materials
- Air/Water Nozzle Flow Path
- Suction Connector Design

Validation from non-clinical testing demonstrated that these technological features do not raise any new issues of safety or effectiveness of the subject device.

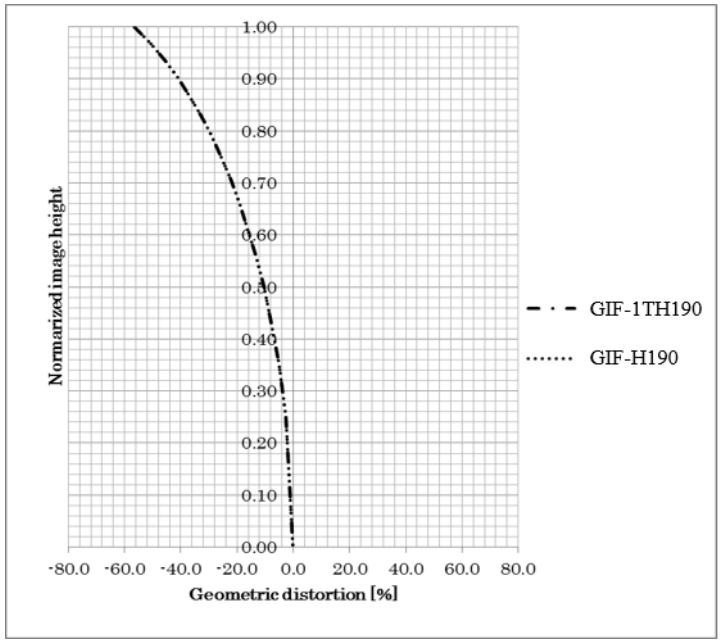
A side-by-side comparison of the subject device and the predicate device is provided

below.

	SUBJECT DEVICE: *EVIS EXERA III GIF-1TH190* *(This Submission)*	PREDICATE DEVICE: *EVIS EXERA III GIF-H190 (K112680)*	REFERENCE DEVICE: *Upper G.I. Scope EG-3490K (K131902)*	COMMENTS ON DIFFERENCE(S)
Manufacturer	**Olympus Medical**	**Olympus Medical**	**Pentax Medical**	-
Device Image				-
Classification & Regulation #	Class II 21 CFR §876.1500	**SAME**	**SAME**	**SAME**
Product Code	**FDS** - Gastroscope And Accessories, Flexible/Rigid, **NWB** - Endoscope, Accessories, Narrow Band Spectrum	**FDF** – Colonoscope And Accessories, Flexible/Rigid **FDS** - Gastroscope And Accessories, Flexible/Rigid, **NWB** - Endoscope, Accessories, Narrow Band Spectrum	**FDS** - Gastroscope And Accessories, Flexible/Rigid	All devices share the same primary product code FDS
Intended Use	Intended to be used with an Olympus video system center,	Intended to be used with an Olympus video system center,	Intended to be used with a	All devices share the same indications for use.

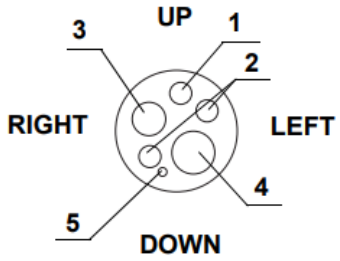
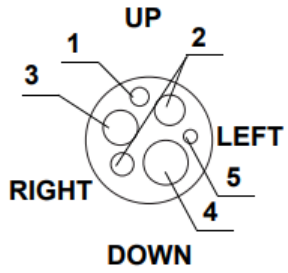
	SUBJECT DEVICE: *EVIS EXERA III GIF-1TH190* *(This Submission)*	PREDICATE DEVICE: *EVIS EXERA III GIF-H190 (K112680)*	REFERENCE DEVICE: *Upper G.I. Scope EG-3490K (K131902)*	COMMENTS ON DIFFERENCE(S)
	light source, documentation equipment, monitor, EndoTherapy accessories (such as a biopsy forceps), 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)	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-H190 is indicated for use within the upper digestive tract (including the esophagus, stomach, and duodenum).	PENTAX video processor (including light source), documentation equipment, monitor, Endotherapy Device such as a Biopsy Forceps, and other ancillary equipment for endoscopy and endoscopic surgery within the upper digestive tract including the esophagus, stomach, and duodenum.	
Optical System Parameters				
Field of View	140°	**SAME**	**SAME**	**SAME**
Direction of View	0° (Forward viewing)	**SAME**	**SAME**	**SAME**
Depth of Field	2-100mm	**SAME**	4-100mm	Same as Primary Predicate

	SUBJECT DEVICE: *EVIS EXERA III GIF-1TH190* *(This Submission)*	PREDICATE DEVICE: *EVIS EXERA III GIF-H190 (K112680)*	REFERENCE DEVICE: *Upper G.I. Scope EG-3490K (K131902)*	COMMENTS ON DIFFERENCE(S)
Optimum Working Distance	8.4 mm	**SAME**	Unknown	Same as Primary Predicate
Resolution at each working distance: on-axis				
• **2 mm**	14.0 lp/mm	**SAME**	Unknown	Same as Primary Predicate
• **8 mm**	17.4 lp/mm	**SAME**	Unknown	
• **100 mm**	1.4 lp/mm	**SAME**	Unknown	
Resolution at each working distance: off-axis (70% of the maximum image height)				
• **2 mm**	15.6 lp/mm	**SAME**	Unknown	Same as Primary Predicate
• **8 mm**	8.7 lp/mm	**SAME**	Unknown	
• **100 mm**	0.6 lp/mm	**SAME**	Unknown	

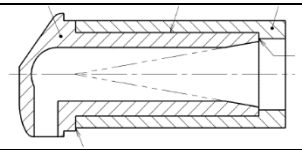
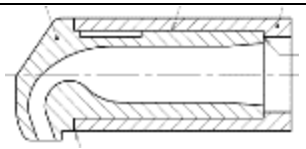
	SUBJECT DEVICE: *EVIS EXERA III GIF-1TH190* *(This Submission)*	PREDICATE DEVICE: *EVIS EXERA III GIF-H190 (K112680)*	REFERENCE DEVICE: *Upper G.I. Scope EG-3490K (K131902)*	COMMENTS ON DIFFERENCE(S)
Distortion (at maximum field of view)			Unknown	Same as Primary Predicate
Imaging System				
Type of Chip	Color CCD	**SAME**	Unknown	Same as Primary Predicate
Number of active	529,731	**SAME**	Unknown	Same as Primary Predicate

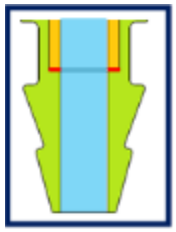
	SUBJECT DEVICE: *EVIS EXERA III GIF-1TH190* *(This Submission)*	PREDICATE DEVICE: *EVIS EXERA III GIF-H190 (K112680)*	REFERENCE DEVICE: *Upper G.I. Scope EG-3490K (K131902)*	COMMENTS ON DIFFERENCE(S)
image Pixels				
Size of Pixels	2.1 µm x 2.1 µm	**SAME**	Unknown	Same as Primary Predicate
Number of Image Sensor Chip	1	**SAME**	Unknown	Same as Primary Predicate
NBI observation	Available	**SAME**	Unknown	The Subject device and primary predicate device have the same imaging units (including image sensor and objective lens) and are compatible imaging systems. NBI function depends on image sensor and objective lens factors, so the effectiveness of the NBI feature is the same between subject device and primary predicate.
Insertion Section				

	SUBJECT DEVICE: *EVIS EXERA III GIF-1TH190* *(This Submission)*	PREDICATE DEVICE: *EVIS EXERA III GIF-H190 (K112680)*	REFERENCE DEVICE: *Upper G.I. Scope EG-3490K (K131902)*	COMMENTS ON DIFFERENCE(S)
Insertion Tube Diameter	**Distal end:** 10.0 mm **Insertion tube:** 10.9 mm **Insertion tube (Maximum):** 13.0 mm	**Distal end:** 9.2 mm **Insertion tube:** 9.2 mm **Insertion tube (Maximum):** 11.2 mm	**Distal end:** 11.5 mm **Insertion tube:** 11.6mm **Insertion tube (Maximum):** 12.85 mm	The subject device has a larger diameter for the instrument channel compared to the predicate device. To ensure that this difference does not affect the safe reprocessing of the subject device, new validation testing was conducted. Please see Section 14 for the details of the reprocessing validation. Additionally, while the diameter of the instrument channel of the subject device is larger when compared to the predicate device, it is smaller than other devices on the market as is shown by the identified

	SUBJECT DEVICE: *EVIS EXERA III GIF-1TH190* *(This Submission)*	PREDICATE DEVICE: *EVIS EXERA III GIF-H190 (K112680)*	REFERENCE DEVICE: *Upper G.I. Scope EG-3490K (K131902)*	COMMENTS ON DIFFERENCE(S)
				reference device (K131902 Pentax EG-3490K scope)
Insertion section Working Length	1030 mm	**SAME**	1050 mm	Same as Primary Predicate
Distal End Enlarged	 1 Air/water nozzle 2 Light guide lens 3 Objective lens 4 Instrument channel outlet	 1 Air/water nozzle 2 Light guide lens 3 Objective lens 4 Instrument channel outlet	Unknown	Similar to predicate.

	SUBJECT DEVICE: *EVIS EXERA III GIF-1TH190* *(This Submission)*	PREDICATE DEVICE: *EVIS EXERA III GIF-H190 (K112680)*	REFERENCE DEVICE: *Upper G.I. Scope EG-3490K (K131902)*	COMMENTS ON DIFFERENCE(S)
	5 Auxiliary water channel	5 Auxiliary water channel		
Instrument Channel				
Channel inner diameter	ø 3.7 mm	ø 2.8 mm	ø 3.8 mm	The subject device has a larger diameter for the instrument channel compared to the predicate device. To ensure that this difference does not affect the safe reprocessing of the subject device, new validation testing was conducted. Please see Section 14 for the details of the reprocessing validation. Additionally, while the diameter of the instrument channel of the subject device is larger when compared to the predicate device, it is smaller than other

	SUBJECT DEVICE: *EVIS EXERA III GIF-1TH190* *(This Submission)*	PREDICATE DEVICE: *EVIS EXERA III GIF-H190 (K112680)*	REFERENCE DEVICE: *Upper G.I. Scope EG-3490K (K131902)*	COMMENTS ON DIFFERENCE(S)
				devices on the market as is shown by the identified reference device (K131902 Pentax EG-3490K scope)
Bending Section				
Angulation Range	Up 210° / Down 90° Right 100° /Left 100°	**SAME**	Up 210° / Down 120° Right 120° /Left 120°	Same as Primary Predicate
Connection to Light Source				
Configuration	Light guide (LG) cable is not detachable	**SAME**	**SAME**	Same as Primary Predicate
Venting Connector				
Position	On the endoscope connector	**SAME**	Unknown	Same as Primary Predicate
Others				
Total length	1350 mm	**SAME**	1383 mm	Same as Primary Predicate
Air/Water nozzle			Unknown	The internal flow path of the air/water nozzle was changed to reduce the occurrence of nozzle

	SUBJECT DEVICE: *EVIS EXERA III GIF-1TH190* *(This Submission)*	PREDICATE DEVICE: *EVIS EXERA III GIF-H190 (K112680)*	REFERENCE DEVICE: *Upper G.I. Scope EG-3490K (K131902)*	COMMENTS ON DIFFERENCE(S)
				clogging. This modification only changes the flow path. The subject device's air/water function remains identical to the predicate device. Therefore, it doesn't affect the safety and effectiveness of the subject device.
Suction Function	Provided	**SAME**	**SAME**	**SAME**
Suction Connector			Unknown	There is a gap inside the Suction connector of the predicate device. The gap is completely removed in the design of the subject device. By removing the gap noted in the Suction Connector, a positive effect is expected in reprocessing validation tests. Therefore, it

	SUBJECT DEVICE: *EVIS EXERA III GIF-1TH190* *(This Submission)*	PREDICATE DEVICE: *EVIS EXERA III GIF-H190 (K112680)*	REFERENCE DEVICE: *Upper G.I. Scope EG-3490K (K131902)*	COMMENTS ON DIFFERENCE(S)
				doesn't affect the safety and effectiveness of the subject device.
Patient-Contacting Materials that Differ				
Distal End of Insertion Section	Polysulfone (P1700-216)	Polysulfone (P1700BK-937)	Unknown	A complete list of patient-contacting materials is listed in **Section 11.5.**
Air/water nozzle of Insertion End	Stainless Steel (SUS303)	Stainless Steel (SUS304)	Unknown	
Instrument channel	(1) PTFE/ePTFE (J-HYPER TUBE) (2) PTFE (6C-J) (3) PTFE (6C-J)	(1) PTFE (6C-J) PTFE/ePTFE (G-HYPER TUBE) (2) PTFE/ePTFE (G-HYPER TUBE) (3) PTFE/ePTFE (G-HYBRID	Unknown	

	SUBJECT DEVICE: *EVIS EXERA III GIF-1TH190* *(This Submission)*	PREDICATE DEVICE: *EVIS EXERA III GIF-H190 (K112680)*	REFERENCE DEVICE: *Upper G.I. Scope EG-3490K (K131902)*	COMMENTS ON DIFFERENCE(S)
		TUBE)		
Compatible Processor / Light Source / Monitor				
Compatible Processor	CV-190	**SAME**	Unknown	Compatibility among the subject endoscope and the compatible processors/light sources/ monitors has been verified successfully. Refer to sections below for more detail. ***Section 16.*** *Software and Cybersecurity* ***Section 17*** *Electrical Safety and Electromagnetic Compatibility* ***Section 18.*** *–Performance Testing - Bench* In addition, the risk analysis has not identified any new or significantly modified risks as it relates to these differences.
Compatible Light Source	CLV-190	**SAME**	Unknown	
Compatible Monitor	OEV262H	OEV261H OEV191H OEV181H OEV191	Unknown	

	SUBJECT DEVICE: *EVIS EXERA III GIF-1TH190* *(This Submission)*	PREDICATE DEVICE: *EVIS EXERA III GIF-H190 (K112680)*	REFERENCE DEVICE: *Upper G.I. Scope EG-3490K (K131902)*	COMMENTS ON DIFFERENCE(S)
				Therefore, it is judged that the safety and effectiveness of the subject device are substantially equivalent to the proposed primary predicate device.
Reprocessing Methods				
Cleaning	Ultrasonic cleaning/ Detergent solution	**SAME**	-	Same as Primary Predicate
Disinfection	2 - 3.5% glutaraldehyde / ACECIDE disinfectant solution	**SAME**	-	Same as Primary Predicate
Sterilization	Ethylene oxide gas sterilization (100% ethylene oxide gas)	**SAME**	-	Same as Primary Predicate

7 PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

1) **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".

2) **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

3) **Electrical safety and electromagnetic compatibility (EMC)**
   Electrical safety and EMC testing was conducted in accordance with the ANSI AAMI ES 60601-1:2005/ (R)2012L and A1:2012, C1:2009/ (R)2012 and A2:2010/ (R)2012 (Consolidated Text) and IEC 60601-2-18:2009 standards for safety and IEC 60601-1-2:2014+A1:2020 standards for EMC.

4) Performance testing - Bench

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

- Thermal safety test
- Composite Durability
- Photobiological safety test
- Noise and Dynamic Range
- Color Performance
- Image Intensity Uniformity
- Distortion
- Field of View
- Direction of View
- Depth of Field
- Video Latency
- Resolution

5) Performance testing - Animal

No animal study was performed to demonstrate substantial equivalence.

6) Performance testing - Clinical

No clinical study was performed to demonstrate substantial equivalence.

7) 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.

8. CONCLUSIONS

Based on the indications for use, technological characteristics, performance testing and technological comparison to the predicate device, the EVIS EXERA III GASTROINTESTINAL VIDEOSCOPE GIF-1TH190 raise no new issue of safety and effectiveness and are substantially equivalent to the predicate device in terms of safety, effectiveness and performance.