July 17, 2020

Olympus Medical Systems Corp.
% Lisa M. Boyle
Regulatory Affairs Specialist II
Olympus Corporation of the Americas
3500 Corporate Parkway PO Box 610
Center Valley, PA 18034-0610

Re: K192793
Trade/Device Name: Evis Exera III Colonovideoscope Olympus PCF-H190TL
Evis Exera III Colonovideoscope Olympus PCF-H190TI
Evis Exera III Colonovideoscope Olympus PCF-HQ190L
Evis Exera III Colonovideoscope Olympus PCF-HQ190I
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FDF, NWB
Dated: September 26, 2019
Received: September 30, 2019

Dear Lisa M. Boyle:

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,

for
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K192793

Device Name
EVIS EXERA III COLONOVIDEOSCOPE OLYMPUS PCF-H190TL/I
EVIS EXERA III COLONOVIDEOSCOPE OLYMPUS PCF-HQ190L/I

Indications for Use *(Describe)*

EVIS EXERA III COLONOVIDEOSCOPE OLYMPUS PCF-H190TL/I
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 COLONOVIDEOSCOPE PCF-H190TL/I is indicated for use within the lower digestive tract (including the anus, rectum, sigmoid colon, colon, and ileocecal valve).

EVIS EXERA III COLONOVIDEOSCOPE OLYMPUS PCF-HQ190L/I
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 COLONOVIDEOSCOPE PCF-HQ190L/I is indicated for use within the lower digestive tract (including the anus, rectum, sigmoid colon, colon, and ileocecal valve).

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.

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Date Prepared: May 29, 2020

510(k) Summary

1. GENERAL INFORMATION

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

■ Contact Person: Lisa M. Boyle
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■ Manufacturing site: Aizu Olympus Co., Ltd.,
500 Muranishi, Niidera, Monden-machi,
Aizuwakamatsu-shi, Fukushima 965-8520, Japan

2. DEVICE IDENTIFICATION

■ Device Name: EVIS EXERA III COLONOVIDEOSCOPE OLYMPUS PCF-H190TL/I
EVIS EXERA III COLONOVIDEOSCOPE OLYMPUS PCF-HQ190L/I

■ Model Name: PCF-H190TL, PCF-H190TI
PCF-HQ190L, PCF-H190I

■ Common Name: COLONOVIDEOSCOPE

■ Regulation Number: 21 CFR 876.1500

■ Regulation Name: Endoscope and accessories

■ Regulatory Class: II

■ Product Code FDF, NWB

■ Classification Panel Gastroenterology/urology

3. PREDICATE DEVICE

■ Predicate device

PCF-H190TL/I

Device name	510(k) Submitter	510(k) No.
EVIS EXERA III VIDEO SYSTEM COLONOVIDEOSCOPE PCF-PH190L/I	OLYMPUS MEDICAL SYSTEMS CORP.	K131780

PCF-HQ190L/I

Device name	510(k) Submitter	510(k) No.
EVIS EXERA III VIDEO SYSTEM COLONOVIDEOSCOPE CF-HQ190L/I	OLYMPUS MEDICAL SYSTEMS CORP.	K131780

■ Reference device

PCF-H190TL/I

Device name	510(k) Submitter	510(k) No.
EVIS EXERA III VIDEO SYSTEM COLONOVIDEOSCOPE PCF-H190L/I	OLYMPUS MEDICAL SYSTEMS CORP.	K131780
PENTAX VIDEO COLONOSCOPES EC-3490TLi	PENTAX MEDICAL COMPANY	K131855

PCF-HQ190L/I

Device name	510(k) Submitter	510(k) No.
EVIS EXERA III VIDEO SYSTEM COLONOVIDEOSCOPE CF-H190L/I	OLYMPUS MEDICAL SYSTEMS CORP.	K131780
PENTAX VIDEO COLONOSCOPES EC-3490TLi	PENTAX MEDICAL COMPANY	K131855

4. DEVICE DESCRIPTION

1) General Description of the subject device

The EVIS EXERA III COLONOVIDEOSCOPE OLYMPUS PCF-H190TL/I and

PCF-HQ190L/I are intended to be used with an Olympus video system center, light source, endoscope position detecting unit (for PCF-HQ190L/I only), documentation equipment, monitor, EndoTherapy accessories (such as a biopsy forceps), and other ancillary equipment for endoscopy and endoscopic surgery. The PCF-H190TL/I and PCF-HQ190L/I are indicated for use within the lower digestive tract (including the anus, rectum, sigmoid colon, colon, and ileocecal valve).

The following items are components and accessories to be marketed with the EVIS EXERA III COLONOVIDEOSCOPE OLYMPUS PCF-H190TL/I and PCF-HQ190L/I.

- Single use combination cleaning brush (BW-412T)
- Injection tube (MH-946)
- Channel plug (MH-944)
- AW channel cleaning adapter (MH-948)
- Suction cleaning adapter (MH-856)
- Auxiliary water tube (MAJ-855)
- ETO cap (MB-156)

Available imaging modes are listed below:

Available imaging modes
WLI
NBI

2) Principle of Operation and Mechanism of Action

The EVIS EXERA III COLONOVIDEOSCOPE OLYMPUS PCF-H190TL/I and PCF-HQ190L/I consist 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 PCF-H190TL/I and PCF-HQ190L/I are identical to that of the predicate devices.

- **Components list of PCF-H190TL/I**

Model	Device Name	510(k) No.
PCF-H190TL/I	EVIS EXERA III COLONOVIDEOSCOPE	Part of this submission

MH-856	Suction cleaning adapter	K131780
MH-948	AW channel cleaning adapter	K131780
MB-156	ETO cap	K131780
MH-944	Channel plug	K131780
MH-946	Injection tube	K131780
MAJ-855	Auxiliary water tube	K131780
BW-412T	Single use combination cleaning brush	510(k) exempt (876.1500, MNL)

■ **Components list of PCF-HQ190L/I**

Model	Device Name	510(k) No.
PCF-HQ190L/I	EVIS EXERA III COLONOVIDEOSCOPE	Part of this submission
MH-856	Suction cleaning adapter	K131780
MH-948	AW channel cleaning adapter	K131780
MB-156	ETO cap	K131780
MH-944	Channel plug	K131780
MH-946	Injection tube	K131780
MAJ-855	Auxiliary water tube	K131780
BW-412T	Single use combination cleaning brush	510(k) exempt (876.1500, MNL)

Components list in the complete system for PCF-H190TL/I and PCF-HQ190L/I

Model	Device Name	510(k) No.
CV-190	EVIS EXERA III video system center	K131780
CLV-190	EVIS EXERA III xenon light source	K131780
OEV262H	High definition LCD monitor	K102379

5. INDICATIONS FOR USE

■ EVIS EXERA III COLONOVIDEOSCOPE PCF-H190TL/I

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 COLONOVIDEOSCOPE PCF-H190TL/I is indicated for use within the lower digestive tract (including the anus, rectum, sigmoid colon, colon, and ileocecal valve).

■ EVIS EXERA III COLONOVIDEOSCOPE PCF-HQ190L/I

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 COLONOVIDEOSCOPE PCF-HQ190L/I is indicated for use within the lower digestive tract (including the anus, rectum, sigmoid colon, colon, and ileocecal valve).

6. COMPARISON OF TECHNOLOGY CHARACTERISTICS WITH THE PREDICATE DEIVCE

The EVIS EXERA III VIDEO SYSTEM COLONOVIDEOSCOPE PCF-H190TL/I has the same technological characteristics and design as the predicate devices except for the following new features:

- Bending section UP Angulation
- Forward water jet
- Insertion section variable stiffness
- Outer Diameter of Distal End
- Outer Diameter of Insertion Tube
- Inner structure of Air/Water nozzle

The EVIS EXERA III VIDEO SYSTEM COLONOVIDEOSCOPE PCF-HQ190L/I has the same technological characteristics and design as the predicate device except for the following new features:

- Outer Diameter of Distal End
- Outer Diameter of Insertion Tube
- Inner Diameter of Instrument Channel
- Inner structure of Air/Water nozzle
- Downsizing of CCD

All other technological characteristics of both the subject and predicate devices are identical. Validation from non-clinical testing demonstrated that these technological features do not raise any new issues of safety or effectiveness of the subject device.

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 for the EVIS EXERA III COLONOVIDEOSCOPE OLYMPUS PCF-H190TL/I and PCF-HQ190L/I were conducted and documentation was 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 for the EVIS EXERA III COLONOVIDEOSCOPE OLYMPUS PCF-H190TL/I and PCF-HQ190L/I 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) Software verification and validation testing

Software verification and validation testing for the EVIS EXERA III COLONOVIDEOSCOPE OLYMPUS PCF-H190TL/I and PCF-HQ190L/I were conducted and documentation was 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".

4) Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the EVIS EXERA III COLONOVIDEOSCOPE OLYMPUS PCF-H190TL/I and PCF-HQ190L/I. The system complies 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.

5) Performance testing - Bench

Bench testing for the EVIS EXERA III COLONOVIDEOSCOPE OLYMPUS PCF-H190TL/I and PCF-HQ190L/I as listed below was conducted to ensure that the subject device performs as intended and meet design specifications.

- Thermal Safety Test
- Composite Durability Test
- Photobiological Safety Test
- Retroflexed Withdrawal and Detection of Hidden Polyps (for PCF-H190TL/I only)

6) Performance testing - Animal

No animal study was performed to demonstrate substantial equivalence.

7) Performance testing - Clinical

A meta-analysis of the clinical performance of NBI for differentiation of diminutive colorectal polyps has been provided in Section 20.1. The clinical literature represents independent studies performed by clinicians with the exception of two Olympus-sponsored studies. The objective of the meta-analysis was to determine the predictive accuracy of endoscopists utilizing NBI and the NBI International Colorectal Endoscopic (NICE) classification or all available classification criteria in general to differentiate diminutive colorectal polyps as neoplastic or non-neoplastic lesions.

The evidence being presented in this premarket notification supports our labeling change of the subject device for the use of Narrow Band Imaging as an adjunctive tool to assist the endoscopist in making predictions of the underlying histology of diminutive polyps. This application does not seek to show superiority or non-inferiority of NBI to the gold standard histopathology.

The results show that pooled data from NBI-experienced and inexperienced endoscopists making high confidence predictions of diminutive polyp histology in real-time provide reasonable certainty of neoplastic vs. non-neoplastic identity. The NICE classification, simplified criteria for distinguishing neoplastic from non-neoplastic polyps, helps the endoscopist achieve similar performance.

8. CONCLUSIONS

Based on the indications for use, technological characteristics, performance testing and technological comparison to the predicate devices, the EVIS EXERA III COLONOVIDEOSCOPE OLYMPUS PCF-H190TL/I and PCF-HQ190L/I raise no new issue of safety and effectiveness and are substantially equivalent to the predicate devices in terms of safety, effectiveness and performance.