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510(k) SUMMARY

EVIS EXERA III VIDEO SYSTEM
ENDOSCOPIC VIDEO IMAGING SYSTEM

January 18, 2012

1 General Information

- Applicant:

OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan 192-8507
Establishment Registration No: 8010047

- Official Correspondent:

Stacy Abbatiello Kluesner, M.S., RAC
Regulatory Affairs & Quality Assurance
Olympus America Inc.
3500 Corporate Parkway
PO Box 610
Center Valley, PA 18034-0610, USA
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- Manufacturer:

(Endoscopes)
Aizu Olympus Co., Ltd.
500 Aza-Muranishi, Ooaza-Iidera, Monden-cho,
Aizuwakamatsu-shi, Fukushima, Japan 965-8520
Establishment Registration No.: 9610595

(CV-190, CLV-190)
SHIRAKAWA OLYMPUS CO., LTD.
3-1, Aza-Ookamiyama, Ooaza-Odakura, Nishigo-mura,
Nishishirakawa-gun, Fukushima, Japan 961-8061
Establishment Registration No: 3002808148

2 Device Identification

- Device Trade Name: EVIS EXERA III VIDEO SYSTEM
- Common Name: ENDOSCOPIC VIDEO IMAGING SYSTEM
- Regulation Number: 876.1500
- Regulation Name: Endoscope and Accessories
- Regulatory Class: II

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- Classification Panel: Gastroenterology and urology
- Product Code: FDF (colonoscope and accessories, flexible/rigid)
  FDS (gastroscope and accessories, flexible/rigid)
  NWB (endoscope, accessories, narrow band spectrum)

3 Predicate Device Information

Subject Device (Part of this submission)	Predicate Device	Predicate Device 510(k) No.
GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF TYPE H190 (GIF-H190)	EVIS EXERA II GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF TYPE H180 (GIF-H180)	K100584
GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF TYPE HQ190 (GIF-HQ190)	EVIS EXERA II GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF TYPE H180 (GIF-H180)	K100584
	EVIS EXERA Gastrointestinal Videoscope GIF-Q160Z (Herein after referred to as GIF-Q160Z)	K011151
COLONOVIDEOSCOPE OLYMPUS CF TYPE HQ190L (CF-HQ190L)	EVIS EXERA II COLONOVIDEOSCOPE OLYMPUS CF TYPE H180AL (CF-H180AL)	K100584
	EVIS EXERA Gastrointestinal Videoscope GIF-Q160Z (Herein after referred to as GIF-Q160Z)	K011151
	Colonovideoscope XCF-Q140L/I3D (Herein after referred to as XCF-Q140L/I3D)	K002749
COLONOVIDEOSCOPE OLYMPUS CF TYPE HQ190I (CF-HQ190I)	EVIS EXERA II COLONOVIDEOSCOPE OLYMPUS CF TYPE H180AI (CF-H180AI)	K100584
	EVIS EXERA Gastrointestinal Videoscope GIF-Q160Z (Herein after referred to as GIF-Q160Z)	K011151
	Colonovideoscope XCF-Q140L/I3D (Herein after referred to as XCF-Q140L/I3D)	K002749
COLONOVIDEOSCOPE OLYMPUS CF TYPE H190L (CF-H190L)	EVIS EXERA II COLONOVIDEOSCOPE OLYMPUS CF TYPE H180AL (CF-H180AL)	K100584
COLONOVIDEOSCOPE	EVIS EXERA II COLONOVIDEOSCOPE	K100584

OLYMPUS CF TYPE H190I (CF-H190I)	OLYMPUS CF TYPE H180AI (CF-H180AI)	
COLONOVIDEOSCOPE OLYMPUS PCF TYPE PH190L (PCF-PH190L)	EVIS EXERA II COLONOVIDEOSCOPE OLYMPUS PCF TYPE H180AL (PCF-H180AL)	K100584
COLONOVIDEOSCOPE OLYMPUS PCF TYPE PH190I (PCF-PH190I)	EVIS EXERA II COLONOVIDEOSCOPE OLYMPUS PCF TYPE H180AI (PCF-H180AI)	K100584
COLONOVIDEOSCOPE OLYMPUS PCF TYPE H190L (PCF-H190L)	EVIS EXERA II COLONOVIDEOSCOPE OLYMPUS PCF TYPE H180AL (PCF-H180AL)	K100584
COLONOVIDEOSCOPE OLYMPUS PCF TYPE H190I (PCF-H190I)	EVIS EXERA II COLONOVIDEOSCOPE OLYMPUS PCF TYPE H180AI (PCF-H180AI)	K100584
OLYMPUS CV-190 VIDEO SYSTEM CENTER (CV-190)	EVIS EXERA Video system Center OLYMPUS CV-160A (CV-160A)	K051645
	EVIS EXERA II VIDEO SYSTEM CENTER OLYMPUS CV-180 (CV-180)	K062049 K100584
OLYMPUS CLV-190 XENON LIGHT SOURCE (CLV-190)	EVIS EXERA Xenon Light Source OLYMPUS CLV-160A (CLV-160A)	K051645
	EVIS EXERA II XENON LIGHT SOURCE OLYMPUS CLV-180 (CLV-180)	K062049 K100584

4 Device Description

The EVIS EXERA III VIDEO SYSTEM consists of Olympus camera heads, endoscopes, video system center, light source, monitors, EndoTherapy accessories and other ancillary equipment for endoscopic diagnosis, treatment and video observation.

The primary components of the subject system, which are part of this submission, are:
- Video System Center OLYMPUS CV-190
- XENON LIGHT SOURCE OLYMPUS CLV-190
- GASTROINTESTINAL VIDEOSCOPE GIF-H190, GIF-HQ190
- COLONOVIDEOSCOPE CF-HQ190L/I, CF-H190L/I, PCF-H190L/I, PCF-PH190L/I

The CV-190 contains the video signal processing technology which enables the endoscope to illuminate, enhance, view, record and transmit video data of endoscopic images. The OLYMPUS CV-190 allows image display on HDTV (16:9).

The XENON LIGHT SOURCE OLYMPUS CLV-190 is intended for endoscopic diagnosis, treatment and video observation.

In addition, both the CV-190 and CLV-190 can be used with any specified Olympus flexible and rigid endoscope models, including gastroscopes, ultrasound gastroscopes, duodenoscopes, colonoscopes, sigmoidscopes, choledochoscopes, bronchoscopes, rhino-laryngoscopes, tracheal intubation scopes, transnasal esophago scopes, hysteroscopes, cystoscopes, ureterorenoscopes, laparo-thoracoscopes.

The subject endoscopes could be used with an Olympus video system center, endoscope position detecting unit (for CF-HQ190L/I), light source, documentation equipment, monitor, EndoTherapy accessories (such as a biopsy forceps), and other ancillary equipment within the upper and lower digestive tract.

5 Indications for Use

Endoscopes
(GASTROINTESTINAL VIDEOSCOPE GIF-H190, GIF-HQ190,
COLONOVIDEOSCOPE CF-HQ190L/I, CF-H190L/I, PCF-H190L/I, PCF-PH190L/I)

This instrument is intended to be used with an Olympus video system center, endoscope position detecting unit (for CF-HQ190L/I), 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, GIF-HQ190 are indicated for use within the upper digestive tract (including the esophagus, stomach, and duodenum).

The EVIS EXERA III COLONOVIDEOSCOPE CF-H190L/I, CF-HQ190L/I, PCF-PH190L/I, PCF-H190L/I are indicated for use within the lower digestive tract (including the anus, rectum, sigmoid colon, colon, and ileocecal valve).

CV-190 VIDEO SYSTEM CENTER
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.

CLV-190 XENON LIGHT SOURCE
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.

6 Comparison of Technological Characteristics

The CV-190 incorporates the following features compared to the predicate device: (1) Provides high quality endoscopic image by using the subject device with new endoscopes and light sources, (2) Noise reduction, (3) Pre-freeze, (4) Brighter and more contrasted NBI observation, (5) Ethernet interface and (6) Color Correction.

The CLV-190 incorporates the following features compared to the predicate device: (1) User friendly new connector, (2) Built-in type power fuse, (3) High-definition images, (4) IR absorbing filter removed.

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The endoscopes incorporates the following features compared to the predicate device: (1) A new Integrated scope connector that includes both the Light-guide and electronic-contact (video scope connection), (2) Dual Focus switching function, LTA (Long Tail Actuator) is incorporated, (3) Passive Bending / High Force Transmission insertion tube and (4) New nozzle.

7 Summary of non-clinical testing

Risk analysis was carried out in accordance with established in-house acceptance criteria based on ISO 14971:2007. The design verifications tests and their acceptance criteria were identified and performed as a result of this risk analysis assessment.

Reprocessing validation was carried out in accordance with "Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance - April 1996."

The software validation activities were performed in accordance with the FDA Guidance, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The device software is considered a "Minor Level of Concern."

The following standards have been applied to the EVIS EXERA III 190 SYSTEM :

- IEC 60601-1
- IEC 60601-1-1
- IEC 60601-2-18
- IEC 60601-1-2
- ISO 14971
- ASTM E1837-96 (Reapproved 2007)
- ANSI/AAMI/ISO 11135-1
- ISO 10993-1
- ISO 10993-5
- ISO 10993-10

8 Conclusion

When compared to the predicate device, the EVIS EXERA III VIDEO SYSTEM does not incorporate any significant changes in intended use, method of operation, material, or design that could affect the safety or effectiveness of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OLYMPUS MEDICAL SYSTEMS CORP.
% Ms. Stacy Abbatiello Kluesner
Project Manager
Olympus America Inc.
3500 Corporate Parkway PO Box 610
CENTER VALLEY PA 18034

FEB 16 2012

Re: K112680
Trade/Device Name: EVIS EXERA III VIDEO SYSTEM
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FDF
Dated: January 19, 2012
Received: January 20, 2012

Dear Ms. Kluesner:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112680

Device Name:

Indications For Use:

Endoscopes (GASTROINTESTINAL VIDEOSCOPE GIF-H190, GIF-HQ190, COLONOVIDEOSCOPE CF-HQ190L/I, CF-H190L/I, PCF-H190L/I, PCF-PH190L/I)

This instrument is intended to be used with an Olympus video system center, endoscope position detecting unit (for CF-HQ190L/I), 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, GIF-HQ190 are indicated for use within the upper digestive tract (including the esophagus, stomach, and duodenum).

The EVIS EXERA III COLONOVIDEOSCOPE CF-H190L/I, CF-HQ190L/I, PCF-PH190L/I, PCF-H190L/I are indicated for use within the lower digestive tract (including the anus, rectum, sigmoid colon, colon, and ileocecal valve).

CV-190 VIDEO SYSTEM CENTER

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.

CLV-190 XENON LIGHT SOURCE

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.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K112680