OLYMPUS
Your Vision, Our Future

510(k) Summary

1. General Information

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

- Official Correspondent: Daphney Germain-Kolawole
  Regulatory Affairs Project Manager
  Olympus Corporation of the Americas
  3500 Corporate Parkway
  PO Box 610
  Center Valley, PA 18034-0610
  Phone: 484-896-5691
  FAX: 484-896-7128

- Prepared Date: June 14, 2013

AUG 2 9 2013

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
- 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 Devices

- EVIS EXERA III VIDEO SYSTEM (K112680)

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 within the upper and lower digestive tract.

The primary components of the subject system are:

- VIDEO SYSTEM CENTER OLYMPUS CV-190
- XENON LIGHT SOURCE OLYMPUS CLV-190
- ENDOSCOPES
  - GASTROINTESTINAL VIDEOSCOPE (GIF-H190,GIF-HQ190, GIF-XP190N)
  - COLONOVIDEOSCOPE (CF-HQ190L/I, CF- H190L/I, PCF- PH190L/I, PCF- H190L/I)

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. Technological Characteristics

The purpose of this notification is to add an additional colonoscopy-related marketing claim to the EVIS EXERA III VIDEO SYSTEM. There are no new technological features incorporated in the EVIS EXERA III VIDEO SYSTEM in this notification. The proposed video system center and xenon light source, and endoscopes have the identical technological features to the predicate devices, respectively. The subject system has been designed to meet the applicable safety standards.

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 purpose of this notification is to add a colonoscopy-related marketing claim to the previous cleared under K112680. No design changes have been made to the EVIS EXERA III VIDEO SYSTEM other than this marketing claim modification.

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 "Moderate Level of Concern."

8. Conclusion

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

August 29, 2013

OLYMPUS MEDICAL SYSTEMS CORP.
% Daphney Germain-Kolawole
Regulatory Affairs Project Manager
Olympus Corporation of the Americas
3500 Corporate Parkway
Center Valley, PA 18034

Re: K131780
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, FDS, NWB
Dated: August 5, 2013
Received: August 6, 2013

Dear Daphney Germain-Kolawole,

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 -S

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): K131780

Device Name: EVIS EXERA III VIDEO SYSTEM

Indications For Use:

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

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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)

Page 1 of 1

Benjamin R. Fisher -S
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