DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

August 7, 2014

OLYMPUS MEDICAL SYSTEMS CORP.
% Sheri L. Musgnung
Manager, Regulatory Affairs
Olympus Corporation of the Americas
3500 Corporate Parkway, PO Box 610
Center Valley, PA 18034-0610

Re: K133538
Trade/Device Name: EVIS EXERA II 180 SYSTEM
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: NWB, FAJ
Dated: June 30, 2014
Received: July 1, 2014

Dear Sheri L. Musgnung,

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,

Herbert P. Lerner -S

for
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K133538

Device Name
EVIS EXERA II 180 SYSTEM

Indications for Use *(Describe)*

VISERA CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF TYPE V2, CYF TYPE VA2, CYF TYPE V2R :
These instruments have been designed to be used with an Olympus video system center, light source, documentation equipment, monitor, EndoTherapy accessories, and other ancillary equipment for endoscopic diagnosis and treatment within the bladder, urethra, ureter, and kidney.

EVIS EXERA II VIDEO SYSTEM CENTER OLYMPUS CV-180 :
This video system center has been designed to be used with Olympus camera heads, endoscopes, light source, monitors, endo-therapy accessories and other ancillary equipment for endoscopic diagnosis, treatment and video observation.

EVIS EXERA II XENON LIGHT SOURCE OLYMPUS CLV-180 :
This light source has been designed to be used with Olympus endoscopes, video system center, and other ancillary equipment for endoscopic diagnosis, treatment and video observation.

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)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 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: Sheri L. Musgnung
  Manager, Regulatory Affairs
  Olympus Corporation of the Americas
  3500 Corporate Parkway
  PO Box 610
  Center Valley, PA 18034-0610, USA
  Phone: 484-896-3147
  FAX: 484-896-7128

- Prepared Date: November 15, 2013

## 2. Device Identification

- Device Trade Name: EVIS EXERA II 180 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: NWB (endoscope, accessories, narrow band spectrum)
  FAJ (cystoscope and accessories, flexible/rigid )

## 3. Predicate Devices

EVIS EXERA II 180 SYSTEM (K062049)

# 4. Device Description

The EVIS EXERA II 180 SYSTEM consists of Olympus camera heads, endoscopes, video system center, light source, monitors, EndoTherapy accessories and other ancillary equipment. This system with the compatible cystscopes is intended for endoscopic diagnosis, treatment and video observation of the bladder, urethra, ureter, and kidney.

The primary components of the subject system are:

- VISERA CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF TYPE V2, CYF TYPE VA2, CYF TYPE V2R (CYF-V2, CYF-VA2, CYF-V2R)
- EVIS EXERA II VIDEO SYSTEM CENTER OLYMPUS CV-180
- EVIS EXERA II XENON LIGHT SOURCE OLYMPUS CLV-180

# 5. Indications for Use

**VISERA CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF TYPE V2, CYF TYPE VA2, CYF TYPE V2R :**
These instruments have been designed to be used with an Olympus video system center, light source, documentation equipment, monitor, EndoTherapy accessories, and other ancillary equipment for endoscopic diagnosis and treatment within the bladder, urethra, ureter, and kidney.

**EVIS EXERA II VIDEO SYSTEM CENTER OLYMPUS CV-180 :**
This video system center has been designed to be used with Olympus camera heads, endoscopes, light source, monitors, endo-therapy accessories and other ancillary equipment for endoscopic diagnosis, treatment and video observation.

**EVIS EXERA II XENON LIGHT SOURCE OLYMPUS CLV-180 :**
This light source has been designed 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 additional urology-related marketing claims to this system, add an additional Cysto-nephro videoscope, add additional compatible items, and add a change to a type of material. There are no new technological features incorporated in this system. The proposed video system center and xenon light source and the subject endoscopes have identical technological features to the predicate device. 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 design verifications tests and their acceptance criteria were identified and performed as a result of this risk analysis assessment.

## 8. Conclusion

When compared to the predicate devices, the EVIS EXERA II 180 SYSTEM does not incorporate any significant changes in intended use, methods of operation, materials, or design that could affect the safety or effectiveness. Based on the design control activities, Olympus believes the EVIS EXERA II 180 SYSTEM and the predicate device selected are substantially equivalent and do not change fundamental scientific technology and intended use of the market-cleared device.