K133311
Page 1 of 2

JUL 30 2014

510(k) Summary of Safety and Effectiveness

1. General information

- Applicant: Olympus Winter & Ibe GmbH
  Kuehnstrasse 61
  22045 Hamburg
  Germany

- Official Correspondent: Sheri L. Musgnung
  Regulatory Affairs & Quality Assurance
  Olympus Corporation of the Americas.
  3500 Corporate Parkway
  PO Box 610
  Center Valley, PA 18034-0610
  Phone: 484-896-5405
  FAX: 484-896-7128
  Email: sheri.musgnung@olympus.com
  Establishment Registration No.: 2429304

- Manufacturer: Olympus Winter & Ibe GmbH
  Kuehnstrasse 61
  22045 Hamburg / Germany

- Registration number: 9610773

- Contact person: Mr. Jan Schueller-Iwersen
  Phone: +49-66966-2860
  Fax: +49-66966-2134
  Email: jan.schueller-iwersen@olympus-oste.eu

2. Device identification

- Proprietary name: EndoLED
- Common name: LED Light Source
- Classification name: LED Light Source
- Regulations Number: 21 CFR 876.1500
- Regulatory class: Class II
- Product code: NTN
- Device panel: Gastroenterology/Urology

3. Predicate devices

K091829 - PLS Portable Light Source by OPTIM Inc., Sturbridge/MA

4. Description of device

The EndoLED is a lightweight portable lamp for the use with endoscopes. The device is battery-operated and uses LEDs to illuminate the area of interest. For the users convenience, the EndoLED come in different designs, the straight and the angled one. The accessories comprise adapters for the use of the EndoLED with different types of endoscopes.

5. Indications of use

The EndoLED is to be used in conjunction with endoscopic devices to provide illumination and visualization of optical images.

6. Comparison of Technological characteristics

The EndoLED shares virtually all specifications and design characteristics of the predicate device. The EndoLED and predicate device are portable detachable light sources for use with rigid and flexible endoscopes. The EndoLED is available in a straight and angled version and the predicate is available in a straight version. The EndoLED utilizes a rechargeable NiMH battery; whereas the predicate device utilizes a rechargeable Lithium Ion battery. Both devices offer the users 40 minutes of use at maximum power. The EndoLED device also features a low battery indicator and houses an integrated cooling element.

7. Summary of non-clinical testing

Risk analysis was carried out in accordance with established in-house acceptance criteria based on ISO-14971:2007.

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 EndoLED:

ISO 14971
IEC 62366
IEC 60601-1
IEC 60601-1-2
IEC 60601-2-18

8 Conclusion

In summary, we believe the EndoLED is substantially equivalent with the predicate device with respect to the general design approach, function, and the indications for use. The EndoLED raises no new concerns of safety or efficacy when compared to the predicate device.

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

July 30, 2014

Olympus Winter & Ibe GmbH
Ms. Sheri L. Musgnung
Regulatory Affairs & Quality Assurance
3500 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K133311
Trade/Device Name: EndoLED Model number WA91500A and WA91502A
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: NTN
Dated: July 1, 2014
Received: July 2, 2014

Dear Ms. 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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical 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)*
K133311

Device Name
EndoLED Model number WA91500A and WA91502A

Indications for Use *(Describe)*
The EndoLED is to be used in conjunction with endoscopic devices to provide illumination and visualization of optical images.

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)*

Neil R Ogden -S
2014.07.28 14:20:53 -04'00'

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."