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510(k) Premarket Notification
ENDOSCOPE REPROCESSOR OER-Pro

FEB 2 3 2011

510(k) Summary

Date Prepared: October 28, 2010

❑ Applicant Information

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

- Official Correspondent: Stacy Abbatiello Kluesner, M.S., RAC
  Regulatory Affairs & Quality Assurance
  OLYMPUS AMERICA INC.
  3500 Corporate Parkway, Center Valley, PA 18034-0610
  Phone: (484) 896-5405
  Fax: (484) 896-7128
  Email: stacy.kluesner@olympus.com
  Establishment Registration No: 2429304

- Manufacturer: AIZU OLYMPUS CO., LTD.
  500 Aza-Muranishi, Ooaza-Iidera, Monden-cho,
  Aizuwakamatsu-shi, Fukushima, Japan 965-8520
  Establishment Registration No: 9610595

❑ Device Identification

- Device Trade Name: ENDOSCOPE REPROCESSOR OER-Pro
- Common Name: Endoscope washer/disinfector
- Class: II
- Regulation Number/Name: 876.1500 Endoscope and accessories
- Product Code: FEB - Accessories, Cleaning, For Endoscope
- Classification Panel: Gastroenterology/Urology
- Performance Standard: None established under Section 514 of FD&C Act.

❑ Predicate Device (PD)

- Device Trade Name: ENDOSCOPE REPROCESSOR OER-Pro
- 510(k) Number: K093106
- Manufacturer: AIZU OLYMPUS CO., LTD.

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- **Device Description**

The OER-Pro Endoscope Reprocessor is an automated endoscope reprocessor intended for high-level disinfection of Olympus flexible endoscopes and its accessories, utilizing both a detergent and FDA cleared high-level disinfectant validated by Olympus to be efficacious and compatible with the materials of the OER-Pro and Olympus flexible endoscopes and accessories.

The OER-Pro is a one-basin automatic endoscope reprocessor that performs leak test, cleaning, disinfection, rinse, and alcohol flush to render a high-level disinfected endoscope and accessories. The OER-Pro utilizes an immersion method for cleaning, disinfecting, and rinsing of endoscope and accessory external surfaces, and connectors for endoscope channel cleaning, disinfecting, and rinsing. Two endoscopes, with several exceptions, can be reprocessed simultaneously in the basin during one reprocessing cycle. The OER-Pro's cleaning cycle includes ultrasonic cleaning, which helps remove debris and dirt from endoscope surfaces.

The OER-Pro is capable of fully automated detergent/disinfectant solution dispensing and alcohol/air drying of endoscope channels. The 0.2-micron air/water filters are bacteria retentive and produce suitable rinse water and air for reprocessing. Built-in sensors detect fluid levels, fluid temperature, air/fluid pressure, and the operating states of the components within the OER-Pro.

The OER-Pro is also equipped with a RFID (Radio-Frequency Identification) function. With a built-in antenna, the OER-Pro is capable of reading user and scope ID data from the proprietary ID tag/chip. The scope/user ID information and each reprocessing result can be printed out with a built-in printer.

The OER-Pro is capable of either using a ready-to-use disinfectant (e.g., Aldahol) or a concentrated disinfectant (e.g., Acecide-C) sealed in dedicated cassette bottles. The concentrated disinfectant is automatically diluted by filtered water until specified quantity in the device. Only Olympus service engineers can switch the disinfection mode.

- **Indications for Use**

The OER-Pro is intended for use in cleaning and high-level disinfection of heat sensitive Olympus flexible endoscopes and their accessories. Safe use requires detergent and an FDA-cleared high-level disinfectant/sterilant that Olympus has validated to be efficacious and compatible with the materials of the OER-Pro and Olympus flexible endoscopes and their accessories. Use of a detergent or high-level disinfectant/sterilant that has not been validated by Olympus may be ineffective and can damage the OER-Pro components and the endoscopes being reprocessed. Endoscopes must be subject to cleaning by the user prior to reprocessing; however, use of the OER-Pro enables the user to perform modified manual cleaning of the endoscope prior to automated cleaning and high-level disinfection in the OER-Pro.

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- **Comparison to Predicate Device**

The OER-Pro is equivalent in indications and operational principles to the predicate device. Subject device is same as the predicate device except using an FDA cleared concentrated disinfectant. In the predicate device, the user pours the FDA cleared ready-to-use disinfectant into the basin without dilution. Compare to the predicate device, the subject device is compatible with the newly validated FDA-cleared concentrated disinfectant solution (Acecide-C), and the software of the subject device can automatically dilute the concentrated disinfectant solution in the tank. In addition, the concentrated disinfectant solution is loaded in a different way from the predicate device.

- **Performance Data**

The OER-Pro has been tested following the requirements in the FDA guidance document titled "Guidance on Premarket Notification [510(k)] Submissions for Automated Endoscope Washers, Washer/Disinfectors, and Disinfectors Intended for Use in Health Care Facilities", issued in August 1993. Test reports provided in this premarket notification include:

Process Parameter Test
The OER-Pro was tested to demonstrate that the device performs as intended. The test results showed that the OER-Pro achieves and maintains the specified physical process parameters, including detection of the defined fault conditions and execution of automatic response/ processing following fault detection.

Validation Testing - Cleaning
The OER-Pro was tested to evaluate its ability to clean endoscopes in both simulated and in-use conditions. The test results demonstrate that the OER-Pro effectively reduced protein and hemoglobin levels in all sample sites.

Validation Testing – High-Level Disinfection
The OER-Pro was tested to evaluate its ability to high-level disinfect endoscopes and valves in both simulated and in-use conditions. The simulated use testing demonstrated a 6 Log_{10} reduction of M.terrae at all inoculated sites was achieved after reprocessing in the OER-Pro's disinfection cycle. In-use testing demonstrated no viable microorganisms were recovered from endoscopes and valves following reprocessing in the OER-Pro.

Validation Testing – Full Cycle
The OER-Pro was tested to evaluate its effectiveness for full cycle reprocessing including both cleaning and disinfection under simulated use conditions. The simulated use testing demonstrated that OER-Pro effectively cleaned and achieved high-level disinfection for Olympus endoscopes and valves.

Simulated-Use Testing – Self-Disinfection
Simulated-use testing was performed to validate self-disinfection of the OER-Pro. Testing demonstrated that a greater than 6 log reduction in M. terrae was achieved for all sample locations after completion of routine reprocessing of endoscopes within the OER-Pro.

Simulated-Use Testing – Water Line Disinfection
The simulated-use testing was performed to validate disinfection of the OER-Pro water line piping which does not contact high-level disinfectant during routine reprocessing.

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The test result showed that a greater than 6 log reduction in M. terrae was achieved for all sample locations after completion of the water line disinfection procedure.

Toxicological Evaluation of Residues
The safety of residual chemicals remaining on endoscopes after reprocessing in the OER-Pro was evaluated. The test results showed that the OER-Pro reprocessing cycle removes detergent and disinfectant residues to non-toxic levels.

❑ Conclusion

The information and performance data presented in this premarket notification support the claim that the OER-Pro is substantially equivalent to the predicate device.

OLYMPUS AMERICA INC.
3500 CORPORATE PARKWAY, P.O. BOX 610, CENTER VALLEY, PA 18034-0610
TELEPHONE (484) 896-5000

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 Corporation
C/O Ms. Stacy Abbatiell Kluesner
Olympus America Incorporated
3500 Corporate Parkway
Center Valley, Philadelphia 18034-0610

FEB 2 3 2011

Re: K103264
Trade/Device Name: ENDOSCOPE REPROCESSOR OER-Pro
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FEB
Dated: January 28, 2011
Received: January 31, 2011

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.

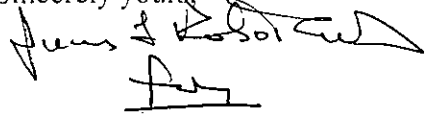
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: ENDOSCOPE REPROCESSOR OER-Pro

Indications For Use:

The OER-Pro is intended for use in cleaning and high-level disinfection of heat sensitive Olympus flexible endoscopes and their accessories. Safe use requires detergent and an FDA-cleared high-level disinfectant/sterilant that Olympus has validated to be efficacious and compatible with the materials of the OER-Pro and Olympus flexible endoscopes and their accessories. Use of a detergent or high-level disinfectant/sterilant that has not been validated by Olympus may be ineffective and can damage the OER-Pro components and the endoscopes being reprocessed. Endoscopes must be subject to cleaning by the user prior to reprocessing; however, use of the OER-Pro enables the user to perform modified manual cleaning of the endoscope prior to automated cleaning and high-level disinfection in the OER-Pro.

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 Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K103264