DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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December 2, 2016

Olympus Medical Systems Corp
% Sheri Musgnung
Manager, Regulatory Affairs
Olympus Corporation of the Americas
3500 Corporate Parkway
P.O. Box 610
Center Valley, PA 18034-0610

Re: K153773
Trade/Device Name: Disposable Lens Cleaning Sheath
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: November 11, 2016
Received: November 14, 2016

Dear Sheri Musgnung,

This letter corrects our substantially equivalent letter of November 22, 2016.

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,

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

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)*
K153773

Device Name
Disposable Lens Cleaning Sheath

Indications for Use *(Describe)*
The Disposable Lens Cleaning Sheath is an endoscope accessory that uses saline solution and carbon dioxide to remove debris from the lens surface of endoscopes used within the thoracic and abdominal cavities, including female reproductive organs

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY
K153773
Disposable Lens Cleaning Sheath

November 22, 2016

5.1 General Information

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

■ Official Correspondent:
Sheri L. Musgnung
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
Email: sheri.musgnung@olympus.com

■ Manufacturer:
OLYMPUS MEDICAL SYSTEMS CORP.
34-3 Hirai, Hinode-machi,
Tokyo, Japan 190-0182
Establishment Registration No.: 3003637092

5.2 Device Identification

■ Device Trade Name: Disposable Lens Cleaning Sheath

■ Common Name: Lens Cleaning Sheath

■ Regulation Number: 876.1500

■ Regulation Name: Endoscope and accessories

■ Regulatory Class: II

■ Classification Panel: General & Plastic Surgery

■ Product Code: GCJ

5.3 Predicate Device Information

Device Trade Name	Common Name	Applicant	510(k) No.
Clear-Vu™ System (Primary predicate device)	endoscope lens cleaning and defogging device	Minimally Invasive Devices, LLC	K080613

The predicate device has not been subject to a design related recall.

5.4 Device Description

The Disposable Lens Cleaning Sheath is an endoscope accessory that uses saline solution and carbon dioxide to remove debris from the lens surface of endoscopes used within the thoracic and abdominal cavities, including female reproductive organs.

The subject device is a single use disposable device and is provided to the user sterile. The subject devices consist of an insertion section, main body section, and water/CO_2 gas tube section.

The subject devices are used in combination with flexible endoscope and rigid endoscope.

Upon use the device is attached to the compatible endoscope, water source, and gas source to remove debris from the objective lens surface of the endoscope by spraying saline solution and CO_2 gas.

5.5 Indications for Use

The Disposable Lens Cleaning Sheath is an endoscope accessory that uses saline solution and carbon dioxide to remove debris from the lens surface of endoscopes used within the thoracic and abdominal cavities, including female reproductive organs.

5.6 Comparison of Technological Characteristics

The subject device and predicate device do not have the same technological characteristics. The construction of the device (thread), component materials (sheath and tip material), water supply, gas supply, and method of sterilization are different.

The different technological characteristics of the subject device do not raise different safety or effectiveness questions as comparable device construction, materials, water supply, gas supply, and methods of sterilization have been evaluated in previous 510(k)s for this device type. Accepted scientific methods exist to assess the effects of the different technological characteristics including electrical, software, and performance testing.

5.7 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 verification tests and their acceptance criteria were identified and performed as a result of this risk analysis assessment.

·Performance testing including sterilization validation, shelf life, and mechanical performance/bench testing was conducted to demonstrate the basic performance of the subject device and confirmed that the subject device performs as intended.

Sterilization validation
Sterilization validation was carried out with Methods VDmax25 in accordance with ISO11137-1:2006.

Shelf life testing
Shelf life testing was conducted based on an accelerated aging test in accordance with ASTM F1980-07(Reapproved 2011), the standard guide for accelerated aging of sterile barrier systems for medical devices. Three years real-time aging test will be performed to demonstrate longer stability and support the results of the accelerated aging test.

Mechanical performance testing
Mechanical performance testing was conducted on the following items to demonstrate the basic performance of the subject device and confirmed that the subject device performs as intended.

- Inserted to the endoscope and remove from the endoscope
- Inserting into the trocar
- Gas feeding operation
- Spray feeding operation
- Inspection of removing the debris
- Insertion section durability
- Fixing strength of the main body
- Inspection of the package

Biocompatibility testing
Biocompatibility testing is performed in accordance with the FDA Guidance," Required Biocompatibility Training and Toxicology Profiles for Evaluation of Medical Devices, Blue Book Memo, G95-1" including cytotoxicity, sensitization, and irritation testing.

·The following standards have been applied to the Disposable Lens Cleaning Sheath.

Standard No.	Standard Title
ISO 10993-1 Fourth Edition:2009-10-15	Biological Evaluation Of Medical Devices - Part1: Evaluation And Testing Within A Risk Management Process [Including: Technical Corrigendum 1 (2010)]
AAMI ANSI ISO 10993-3:2003/(R)2013	Biological Evaluation Of Medical Devices Part 3: Tests For Genotoxicity, Carcinogenicity And Reproductive Toxicity
AAMI ANSI ISO 10993-5:2009/(R)2014	Biological Evaluation Of Medical Devices – Part5: Tests For In Vitro Cytotoxicity
ISO 10993-10 Third Edition: 2010-08-01	Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization
AAMI/ANSI/ISO 10993-11: 2006/(R)2010	Biological Evaluation Of Medical Devices Pat11 : Tests For Systemic Toxicity
ISO 11137-1 First Edition: 2006-04-15	Sterilization Of Health Care Products - Radiation - Part 1: Requirements For Development, Validation And Routine Control Of A Sterilization Process For Medical Devices [Including: Amendment 1 (2013)]
ISO 11137-2 Third Edition: 2013-06-01	Sterilization Of Health Care Products - Radiation - Part 2: Establishing The Sterilization Dose
ASTM F1980-07 (Reapproved 2011)	Standard Guide For Accelerated Aging Of Sterile Barrier Systems For Medical Devices
ISO 14971 Second Edition: 2007-03-01	Medical Devices - Application Of Risk Management To Medical Devices

5.8 Conclusion

The Disposable Lens Cleaning Sheath is substantially equivalent to the proposed predicate device.