March 29, 2018

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

Re: K172298
Trade/Device Name: Olympus URF-P6/P6R
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FGB, FBN
Dated: February 23, 2018
Received: February 26, 2018

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.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Charles Viviano -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)*
K172298

Device Name
Olympus URF-P6/P6R

Indications for Use *(Describe)*
This instrument has been designed to be used with an Olympus light source, documentation equipment, monitor, EndoTherapy accessories, and other ancillary equipment for endoscopic diagnosis and treatment within the ureter, kidney and biliary tract (common bile duct and hepatic duct).

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

February 23, 2018

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
  Regulatory Affairs
  Olympus America Inc.
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  PO Box 610
  Center Valley, PA 18034-0610, USA
  Phone: 484-896-3147
  FAX: 484-896-7128
  Email: sheri.musgnung@olympus.com

- Manufacturer: Aizu Olympus Co., Ltd.
  500 Aza-Muranishi, Ooaza-Iidera, Monden-cho,
  Aizuwakamatsu-shi, Fukushima, Japan 965-8520
  Establishment Registration No.: 9610595

2. Device Identification

- Device Trade Name: OLYMPUS URF-P6/P6R,
- Common Name: URETERO-RENO FIBERSCOPE
- Regulation Number: 876.1500
- Regulation Name: Endoscope and Accessories
- Regulatory Class: II
- Classification Panel: Gastroenterology and urology
- Product Code: FGB (Ureteroscope and accessories, flexible/rigid)
- Secondary Product Code: FBN (Choledochoscope and accessories, flexible/rigid)

3. Predicate Device

K912120 URETERORENOSCOPE OLYMPUS URF TYPE P2

4. Device Description

This endoscope is composed from eyepiece section, control section and flexible insertion tube, and equipped light fiber bundle for image transfer system. Besides, it has eyepiece frame on eyepiece section for eyepiece and video camera connection for endoscope.

URF-P6R has Identification marking for opposite bending direction on the control section and the bending section of the URF-P6R moves in the direction opposite to the conventional endoscopes, such as the URF-P6. This is the only different point between URF-P6 and URF-P6R.

5. Indications for Use

This instrument has been designed to be used with an Olympus light source, documentation equipment, monitor, EndoTherapy accessories, and other ancillary equipment for endoscopic diagnosis and treatment within the ureter, kidney and biliary tract (common bile duct and hepatic duct).

The Indications for Use statement for the OLYMPUS URF-P6/P6R is not literally identical to the predicate device; however, the meanings of their descriptions are the same. Both of the subject and predicate device have the same intended use for the endoscopic diagnosis and treatment of urinary tract and biliary tract.

6. Comparison of Technological Characteristics

Compared to the predicate device, the subject device differs as it relates to labeling, technology/ engineering/ performance, and materials. The main modifications are as follows:

1. The physical properties of the insertion section and optical parameters are slightly changed.
2. The patient-contact material is changed.
3. Sterilization method by hydrogen peroxide is added.
4. Internal structure is improved to enhance the mechanical durability.

Validation from non-clinical testing demonstrated that these technological features do not raise any new issues of safety or effectiveness of the subject device.

A side by side comparison of the subject device and the predicate device is provided below.

Item	<Subject Device> URF-P6/P6R	<Predicate Device> URF-P2 (K912120)
Indications for use	This instrument has been designed to be used with an Olympus light source, documentation equipment, monitor, EndoTherapy accessories, and other ancillary equipment for endoscopic diagnosis and treatment within the ureter, kidney and biliary tract (common bile duct and hepatic duct).	The Olympus URF Type P2 has been designed for endoscopic observation and diagnosis within both the urinary tract (ureter, renal pelvis, and renal calyx) and biliary tract (common bile duct and hepatic duct.) Therapeutic endoscopic procedures using various kinds of accessories are also possible, and include the ability to extract or fragment stones within these organs.
Common name	URETERO-RENO FIBERSCOPE	URETERO-RENO FIBERSCOPE
Regulation number	876.1500	876.1500
Regulation name	Endoscope and Accessories	Endoscope and Accessories
Regulatory class	II	II
Classification panel	Gastroenterology and urology	Gastroenterology and urology
Product code	FGB, FBN	FBN, FGB
Environment of use	Healthcare facility/hospital	Healthcare facility/hospital
Single/repeat use	Repeat use	Repeat use
Sterile/non-sterile	Marketed as non-sterile	Marketed as non-sterile
Sterilization method	Ethylene oxide; Hydrogen peroxide	Ethylene oxide;
Energy source	Electricity	Electricity
Material composition of main patient-contact parts and duration and type of contact	Material composition of main patient-contact parts Distal end: polysulfone Insertion tube: fluoro resin Bending rubber: fluoro rubber Lens: glass Adhesive: ES-19MC Surface-contacting device in contact with mucosal membranes. The contact duration is limited exposure (i.e. contact is up to 24 hours).	Material composition of main patient-contact parts Distal end: stainless Insertion tube: polyurethane resin Bending rubber: fluoro rubber Lens: glass Adhesive: ES-8SC Surface-contacting device in contact with mucosal membranes. The contact duration is limited exposure (i.e. contact is up to 24 hours).

7. Summary of Non-clinical Testing

The technological characteristic differences between the predicate device and the subject device have been confirmed that they are substantially equivalent through the following tests and standards.

•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.

•Biocompatibility testing is performed in accordance with the FDA Guidance, Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a risk management process" issued on June 16 2016.

•Performance testing was carried out to verify the safety and the effectiveness of the subject device.

•The reprocessing validation test was performed in accordance with the FDA guidance "Guidance for Industry and FDA Staff - Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling issued on March 17, 2015"

•Electric safety has been validated in accordance with FDA`s currently recognized standards.

The results of the above performance testing demonstrated that the subject device has no concerns on safety and effectiveness.

Also, the following standards have been applied to the subject device:

Standard No.	Standard Title
ISO 14971 Second Edition: 2007-03-01	Medical Devices - Application Of Risk Management To Medical Devices
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 10993-5:2009/(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

Standard No.	Standard Title
AAMI ANSI ES60601-1:2005/(R)2012 and A1:2012	Medical Electrical Equipment – Part 1: General Requirements for Basic Safety And Essential Performance + Amendment 1: 2012
IEC 60601-2-18 Edition 3.0: 2009-08	Medical Electrical Equipment - Part 2-18: Particular Requirements For The Basic Safety And Essential Performance Of Endoscopic Equipment.

8. Conclusion

In comparison to the predicate device, Olympus URF-P6/P6R has the same intended use and the technical differences do not cause any significant changes that could affect the safety or effectiveness of the device. Therefore, the subject device is substantially equivalent to the predicate device.