January 16, 2019

Olympus Medical Systems Corp.
% Sheri L. Musgnung
Regulatory Affairs Manager
Olympus Surgical Technologies America
3500 Corporate Parkway P.O. Box 610
Center Valley, PA 18034-0610

Re: K181451
Trade/Device Name: OLYMPUS URF-V3/V3R, OLYMPUS URF-P7/P7R
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FGB, NWB
Dated: December 5, 2018
Received: December 6, 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 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,

Mark R. Kreitz -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)*
K181451

Device Name
OLYMPUS URF-V3/V3R, OLYMPUS URF-P7/P7R

Indications for Use *(Describe)*

-OLYMPUS URF-V3/V3R

This instrument has 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 ureter and kidney.

-OLYMPUS URF-P7/P7R

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.

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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."

May 31, 2018

Section 5

510(k) Summary

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 Surgical Technologies America
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 Aizu Olympus Co., Ltd.,
500 Muranishi, Niidera, Monden-machi,
Aizuwakamatsu-shi, Fukushima 965-8520, Japan
Establishment Registration No.: 9610595

5.2 DEVICE IDENTIFICATION

URETERO-RENO VIDEOSCOPE OLYMPUS URF-V3/V3R

■ Device Name: OLYMPUS URF-V3/V3R

■ Common Name: URETERO-RENO VIDEOSCOPE

■ Regulation Number: 876.1500

■ Regulation Name: Endoscope and Accessories

■ Regulatory Class: II

■ Product Code: FGB (Ureteroscope And Accessories, Flexible/Rigid)
NWB (Endoscope, accessories, narrow band spectrum)

■ Classification Panel: Gastroenterology and urology

URETERO-RENO FIBERSCOPE OLYMPUS URF-P7/P7R

■ Device Name OLYMPUS URF-P7/P7R

■ Common Name URETERO-RENO FIBERSCOPE

■ Regulation Number 876.1500

■ Regulation Name Endoscope and Accessories

■ Regulatory Class II

■ Product Code FGB (Ureteroscope And Accessories, Flexible/Rigid)
FBN (Choledochoscope And Accessories, Flexible/Rigid)

■ Classification Panel Gastroenterology and urology

5.3 PREDICATE DEVICE

URETERO-RENO VIDEOSCOPE OLYMPUS URF-V3/V3R

Table 5-1 Predicate device

Device name	510(k) Submitter	510(k) No.
OLYMPUS URF-V2/V2R	OLYMPUS MEDICAL SYSTEMS CORP.	K172246

URETERO-RENO FIBERSCOPE OLYMPUS URF-P7/P7R

Table 5-2 Predicate device

Device name	510(k) Submitter	510(k) No.
OLYMPUS URF-P6/P6R	OLYMPUS MEDICAL SYSTEMS CORP.	K172298

5.4 DEVICE DESCRIPTION

URETERO-RENO VIDEOSCOPE OLYMPUS URF-V3/V3R

URF-V3 and URF-V3R 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 ureter and kidney.

This endoscope is a videoscope, composed of flexible insertion tube, control section, light guide connector and video connector, and equipped CCD for image transfer system. The difference between URF-V3 and URF-V3R is angle operation direction. The bending section of the URF-V3R moves towards the direction oppositely to that of the URF-V3.

URETERO-RENO FIBERSCOPE OLYMPUS URF-P7/P7R
URF-P7 and URF-P7R have 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).
This endoscope is a fiberscope, composed of flexible insertion tube, control section and eyepiece section, and equipped light fiber bundle for image transfer system. Besides, it has eyepiece frame on eyepiece section for directly visual observation or video camera connection.
The difference between URF-P7 and URF-P7R is angle operation direction. The bending section of the URF-P7R moves towards the direction oppositely to that of the URF-P7.

5.5 INDICATIONS FOR USE

URETERO-RENO VIDEOSCOPE OLYMPUS URF-V3/V3R
This instrument has 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 ureter and kidney.

URETERO-RENO FIBERSCOPE OLYMPUS URF-P7/P7R
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).

5.6 COMPARISON OF TECHNOLOGY CHARACTERISTICS WITH THE PREDICATE DEIVCE

The URF-V3/V3R and URF-P7/P7R have the same technological characteristics and design as their predicate devices except for the following main features:

- Improvement of passive bending section in the insertion section.
- Addition of compatible sterilization methods.

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

All other technological characteristics of both the subject and predicate devices are identical.

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

Table 5-3 Comparison of URF-V3/V3R and their predicate devices.

Item	<Subject Device> OLYMPUS URF-V3/V3R	<Predicate Device> OLYMPUS URF-V2/V2R (K172246)
Indications for use	This instrument has 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 ureter and kidney.	This instrument has 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 ureter and kidney.
Common name	URETERO-RENO VIDEOSCOPE	URETERO-RENO VIDEOSCOPE
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, NWB	FGB, NWB
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 including V-PRO maX and STERRAD NX/100NX (with or without ALLClear Technology).	Ethylene oxide; Hydrogen peroxide including STERRAD NX/100NX.
Energy source	Electricity	Electricity

Item	<Subject Device> OLYMPUS URF-V3/V3R	<Predicate Device> OLYMPUS URF-V2/V2R (K172246)
Material composition of main patient-contact parts and duration and type of contact	Material composition of main patient-contact parts Distal end: Stainless steel Insertion tube: Fluoro resin Bending section rubber: Fluoro rubber Lens: Glass Glue: Epoxy glue 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 steel Insertion tube: Fluoro resin Bending section rubber: Fluoro rubber Lens: Glass Glue: Epoxy glue Surface-contacting device in contact with mucosal membranes. The contact duration is limited exposure (i.e. contact is up to 24 hours).

Table 5-4 Comparison of URF-P7/P7R and their predicate devices.

Item	<Subject Device> OLYMPUS URF-P7/P7R	<Predicate Device> OLYMPUS URF-P6/P6R (K172298)
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).	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).
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

Item	<Subject Device> OLYMPUS URF-P7/P7R	<Predicate Device> OLYMPUS URF-P6/P6R (K172298)
Single/repeat use	Repeat use	Repeat use
Sterile/non-sterile	Marketed as non-sterile	Marketed as non-sterile
Sterilization method	Ethylene oxide; Hydrogen peroxide including V-PRO maX and STERRAD NX/100NX.	Ethylene oxide; Hydrogen peroxide including STERRAD NX/100NX.
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 section rubber: Fluoro rubber Lens: Glass Glue: Epoxy glue 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: Polysulfone Insertion tube: Fluoro resin Bending section rubber: Fluoro rubber Lens: Glass Glue: Epoxy glue Surface-contacting device in contact with mucosal membranes. The contact duration is limited exposure (i.e. contact is up to 24 hours).

5.7 Summary of non-clinical testing

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

- Reprocessing instruction and reprocessing method validation testing for the URF-V3/V3R and, URF-P7/P7R were assessed and documentation was provided as recommended by Guidance for Industry and Food and Drug Administration Staff, “Reprocessing Medical Devices in Health Care Setting: Validation Methods and Labeling”.

- Biocompatibility testing was 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.

•Software verification and validation testing including the requirement of cybersecurity for the URF-V3/V3R were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" and "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices".

•Electrical safety and electromagnetic compatibility (EMC)
Electrical safety and EMC were assessed for the URF-V3/V3R. The system complies with the ANSI/AAMI ES 60601-1:2005/A2:2010/(R) 2012 and IEC 60601-2-18:2009 standards for electrical safety and the IEC 60601-1-2:2014 standards for EMC.
Electrical safety was assessed for the URF-P7/P7R The system complies with the ANSI/AAMI ES 60601-1:2005/A2:2010/(R) 2012 and IEC 60601-2-18:2009 standards for electrical safety.

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

•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.

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

·The following standards have been applied to the URETERO-RENO VIDEOSCOPES

Table 5.3 Standards for URETERO-RENO VIDEOSCOPE OLYMPUS URF-V3/V3R

Standard number	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)]
ISO 10993-5 Third Edition:2009-06-01	Biological Evaluation Of Medical Devices – Part5: Tests For In Vitro Cytotoxicity
ISO 10993-7 Second Edition:2008-10-15	Biological Evaluation Of Medical Devices - Part 7: Ethylene Oxide Sterilization
ISO 10993-10 Third Edition: 2010-08-01	Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization

ISO 14971 Second Edition:2007-03-01	Medical Device-Application Of Risk Management To Medical Device
AAMI ANSI ES60601-1: 2005/ (R)2012 and A1:2012,	C1:2009/(R)2012 And A2:2010/(R)2012 (Consolidated Text) Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (IEC 60601-1:2005, MOD)
IEC 60601-1-2 Edition 4: 2014-02	Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests
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
ISO 11135 Second Edition:2014	Sterilization Of Health-Care Products Ethylene Oxide-Requirements For The Development, Validation And Routine Control Of A Sterilization Process For Medical Devices

·The following standards have been applied to the URETERO-RENO VIDEOSCOPE

Table 5.4 Standards for URETERO-RENO FIBERSCOPE OLYMPUS URF-P7/P7R

Standard number	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)]
ISO 10993-5 Third Edition:2009-06-01	Biological Evaluation Of Medical Devices – Part5: Tests For In Vitro Cytotoxicity
ISO 10993-7 Second Edition:2008-10-15	Biological Evaluation Of Medical Devices - Part 7: Ethylene Oxide Sterilization
ISO 10993-10 Third Edition: 2010-08-01	Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization
ISO 14971 Second Edition:2007-03-01	Medical Device-Application Of Risk Management To Medical Device
AAMI ANSI ES60601-1:	C1:2009/(R)2012 And A2:2010/(R)2012 (Consolidated

2005/ (R)2012 and A1:2012,	Text) Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (IEC 60601-1:2005, MOD)
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
ISO 11135 Second Edition:2014	Sterilization Of Health-Care Products Ethylene Oxide-Requirements For The Development, Validation And Routine Control Of A Sterilization Process For Medical Devices

5.8 CONCLUSIONS

Based on the intended use and technological comparison to the predicate devices, the subject devices OLYMPUS URF-V3/V3R and OLYMPUS URF-P7/P7R are demonstrated to raise no new issue of safety and effectiveness and are substantially equivalent to their predicate devices in terms of safety and effectiveness.