August 28, 2020

Olympus Winter & Ibe GmbH
% Christina Flores
Regulatory Affairs Manager
Olympus Surgical Technologies America
118 Turnpike Road
Southborough, MA 01772-2104

Re: K200369
Trade/Device Name: OES Elite Ureteroscopes and Accessories (WA2UR11A, WA2UR12A, WA2UR13A, WA2UR14A, WA2UR21A, WA2UR22A, WA2UR23A, WA2UR31A, WA2UR32A, WA2URADP, WA47778A)
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FGB
Dated: August 3, 2020
Received: August 4, 2020

Dear Christina Flores:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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 J. Antonino, M.S.
Acting Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

Device Name
OES Elite Ureteroscopes and Accessories (WA2UR11A, WA2UR12A, WA2UR13A, WA2UR14A, WA2UR21A, WA2UR22A, WA2UR23A, WA2UR31A, WA2UR32A, WA2URADP, WA47778A)

Indications for Use *(Describe)*
The Olympus ureteroscopes can be utilized for endoscopic observation and therapy in the ureters, urethra, and urinary bladder.
Semi-rigid optical instrument for the visualization of the following diagnostic and therapeutic procedures:
- Transurethral inspection of the ureters and renal pelvis for diagnosis
- Transurethral insertion of catheters, guide wires, cannulas, forceps, electrodes, baskets, lithotripsy probes and laser fibres into the ureter
- Transurethral treatment and removal of tissue, catheters, guide wires, debris and stones from urethra, urinary bladder and ureters
- Transurethral treatment and removal of tissue and stones from the ureters and renal pelvis.

The products are not intended for treatment of infants. For children (>2 years) and adults, refer to the particular constitution and anatomy of the patient.

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.

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510(k) Summary

August, 3rd, 2020

1. General Information

- **Manufacturer/Holder** Olympus Winter and Ibe GmbH
  Kuehnstr. 61
  22045 Hamburg
  Germany
  Establishment Registration No.: 9610773

- **Official Correspondent** Ms. Christina Flores, RAC
  Olympus Surgical Technologies America
  118 Turnpike Road
  Southborough, MA 01772
  Phone: (508) 808-3341
  Email: Christina.Flores@olympus.com
  Establishment Registration No.: 3003790304

2. Device Identification

- **Device Trade Name:** OES Elite Ureteroscopes and Accessories (WA2UR11A, WA2UR12A, WA2UR13A, WA2UR14A, WA2UR21A, WA2UR22A, WA2UR23A, WA2UR31A, WA2UR32A, WA2URADP, WA47778A)
- **Common Name:** Ureteroscopes
- **Classification Name:** Endoscope and Accessories
- **Regulation Number:** 21 CFR 876.1500
- **Product Code:** FGB
- **Product Code Name:** Ureteroscope and Accessories, Flexible/Rigid
- **Regulatory Class:** II

3. Predicate Devices

K052044, ACMI® MR-6A/MR-6LA Autoclavable Ureteroscopes

K011849, MRO-742A Ureteroscope

No reference devices were used in this submission.

4. Device Description

The OES Elite Ureteroscopes are inserted directly through the natural orifice urethra and are used to visualize a wide range of therapeutic procedures or to support diagnosis. The OES Elite Ureteroscopes are reusable semi-rigid endoscopes, which consist of an image relay system inside the main body and an outer tube that guides an image fiber bundle to transmit the endoscopic image. For therapeutic procedures, the device is used in combination with surgical instruments which can be introduced through the instrument channels.

The OES Elite Ureteroscopes and accessories are delivered in non-sterile condition. They are reusable and fully reprocessable. Before first and each subsequent use the device must be inspected and reprocessed according to defined and validated reprocessing methods in the instructions for use.

The OES Elite Ureteroscopes are available in different working lengths, ocular directions, image sizes, directions of views and with one or two instrument channels.

5. Indications for Use

The Olympus ureteroscopes can be utilized for endoscopic observation and therapy in the ureters, urethra, and urinary bladder.
Semi-rigid optical instrument for the visualization of the following diagnostic and therapeutic procedures:

- *Transurethral inspection of the ureters and renal pelvis for diagnosis*
- *Transurethral insertion of catheters, guide wires, cannulas, forceps, baskets, lithotripsy probes and laser fibers into the ureter*
- *Transurethral treatment and removal of tissue, catheters, guide wires, debris and stones from urethra, urinary bladder and ureters*
- *Transurethral treatment and removal of tissue and stones from the ureters and renal pelvis.*

The products are not intended for treatment of infants. For children (>2 years) and adults, refer to the particular constitution and anatomy of the patient.

The indications for use statement for the subject OES Elite Ureteroscopes is very similar to that of the predicate devices. A slightly different wording is chosen and specific indications are added, listing specific diagnostic and therapeutic procedures. Also, the patient population excludes the treatment of infants. .
The differences do not alter the intended use of the device nor do they raise different questions of safety and effectiveness of the device relative to the predicate.

6. Summary of Technological Characteristics

The technological characteristics of the subject devices are considered equivalent to the predicate devices. Details can be found in the following table.

Characteristic	*Subject Devices*	*Predicate Devices*
General technology	A ureteroscope is a semi-rigid endoscope. An image relay system of image fibers transmits the endoscopic image. A bundle of optical fibers transmits light from a light source to illuminate the operating field	Same as subject device
Distal end	Functional components: objective cover glass, instrument channel(s), light emission surface	Same functional component as subject device.
Proximal end	All distal ends have the following functional components: irrigation connector, instrument port, eyepiece cup, finger rests and light guide connector. Some models have incorporated stopcocks. The subject device models differ in the positioning of these elements and the design of the finger rests. Some models are available with angled others with straight ocular.	Same functional components as subject device, exept for built-in stopcocks and finger rests.
Insertion tube	Profile form distal: Triangular (dual-channel) and oval (single-channel).	Profile form distal: Triangular (dual-channel) and oval (single-channel), but minor differences exist.
Irrigation inflow	0.7 ml/min - 9.7ml/min with inserted wire	0.2 ml/min - 17 ml/min with inserted wire
Maximum working length	(330 mm - 430 mm) ± 1 mm	(330 mm - 430 mm) ± 5 mm
Outer circumference on distal tip	(8.4 Fr - 10.4 Fr) ± 0.4 Fr.	7 Fr - 8.4 Fr
Maximum insertion portion width	11.7 Fr. - 13.05 Fr.	10.2 Fr - 11.2 Fr
Minimum instrument channel width	2.4 Fr. - 5.4 Fr.	2.3 Fr - 5.4 Fr
Direction of view	5° ± 5° or 0° ± 5°	5° ± 3°
Field of view	(86° - 95°) ± 12°	61° ± 3°
Illumination	Minimum: (0.081 - 0.150) mlm/klx	(0.193 - 0.277) mlm/klx
Resolution	≥ 9.5 lp/mm @ best working distance	≥ 5 lp/mm @ best working distance
Distortion	Relative Distortion in air (max value): -40.0%	Relative Distortion in air (max value): -19.8 %
Moiré filter	Included	Not included
Total number of fibers/pixels	30000 pixel or 50000 pixel	30000 pixel
Automated cleaning	yes	no
Autoclavibility	yes	yes

As stated above, the subject and predicate devices have similar design characteristics and show comparable performance. As demonstrated in the nonclinical testing the different technological characteristics do not raise any new questions of safety and effectiveness when compared to the predicate device.

7. Performance Data

The following design verification and validation testing was performed on the subject devices to ensure that the subject devices function as intended and meet design specifications:

- Electrical safety as per ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012 and IEC 60601-2-18 Edition 3.0
- Thermal safety as per ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012 and IEC 60601-2-18 Edition 3.0
- Mechanical and optical performance testing as per ISO 8600-1 Edition 4, ISO 8600-3 Edition 1 and ISO 8600-4 Edition 2
- Transport and shipping testing as per ASTM D4169-16
- Tests related to the expected service life as per ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012 and IEC 60601-2-18 Edition 3.0
- Biocompatibility testing according ISO 10993-1 Ed. 5: 2018
- Reprocessing validation was conducted in accordance with the FDA guidance document “Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling” issued March 17, 2015.
- Usability validation was conducted according to IEC 62366-1 Ed. 1.0: 2015 and IEC 60601-1-6 Ed. 3.1: 2013. Usability Validation of the Instructions for Use as per FDA guidance document “Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling” issued March 17, 2015.
- Additional comparative testing: Visible image size, distortion, internal reflections, vignetting, transmission of the optical system, transmission of the illumination system, light distribution of illumination, remaining deformation after bending stress, flow rate in first and second instrument channel

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

8. Conclusion

The performance data support the safety of the device and demonstrate that the subject devices comply with the recognized standards as specified and support a substantial equivalence determination.