September 15, 2021

Olympus Winter & Ibe GmbH
% Dolan Mills
Principal Specialist, Regulatory Affairs
Olympus Surgical Technologies America
118 Turnpike Road
Southborough, Massachusetts 01772

Re: K203492
Trade/Device Name: Instrument tray, for semi-rigid ureteroscope
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: August 9, 2021
Received: August 10, 2021

Dear Dolan Mills:

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,

Clarence W. Murray III -S

Clarence W. Murray, III, PhD
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203492

Device Name
Instrument tray, for semi-rigid ureteroscope

Indications for Use *(Describe)*
The instrument tray is intended to be used to enclose and protect one Olympus semi-rigid ureteroscope, models WA2UR11A, WA2UR12A, WA2UR13A, WA2UR14A, WA2UR21A, WA2UR22A, WA2UR23A WA2UR31A, and WA2UR32A (K200369), and accessories during sterilization in a prevacuum steam sterilizer using the following parameters or cycles:

Prevacuum steam sterilization
- Exposure time at a temperature of 132 °C (269.6 °F:)
Wrapped instruments .....4 min.
Unwrapped non-porous instruments .....3 min.

- Exposure time at a temperature of 135 °C (275 °F:)
Wrapped instruments .....3 min.
Unwrapped non-porous instruments .....3 min.

- Drying time.....30 min.

After steam sterilization, let the instrument tray cool down at room temperature.
- Cool-down time.....30 min.

The instrument tray is also intended for the enclosure of Olympus semi-rigid ureteroscopes and accessories during transport and storage within the reprocessing cycle. The instrument tray is not compatible with flexible ureteroscopes.

The instrument tray is to be used in conjunction with a FDA cleared sterilization wrap. Maintenance of sterility depends on the sterilization wrap.

Worst case load:
The instrument tray containing a ureteroscope, attachments, light-guide cable, light-guide cable adapters, sealing caps and stopcocks must not exceed a weight of 3300 grams (7.27 lb) altogether.

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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2 510(k) Summary, K203492

2.1 General Information

Manufacturer:	Olympus Winter & Ibe GmbH Kuehnstr. 61 22045 Hamburg Germany Establishment Registration Number: 9610773
Official Correspondent:	Dolan Mills Program Manager, Regulatory Affairs Gyrus ACMI, Inc. 800 West Park Drive Westborough, MA 01581 Phone: (901) 373-0236 Email: dolan.mills@olympus.com Establishment Registration Number: 3003790304
Date Prepared:	Sept 15, 2021

2.2 Device Identification

Proprietary name:	Instrument tray, for semi-rigid ureteroscope
Device Classification name:	Sterilization Wrap Containers, Trays, Cassettes & Other Accessories
Regulation Medical Specialty:	General Hospital
Regulation Number; Name:	21CFR 880.6850; Sterilization wrap.
Product code; name; class:	KCT; Sterilization Wrap Containers, Trays, Cassettes & Other Accessories; class II

2.3 Predicate Device

The applicant device, Instrument tray, for semi-rigid ureteroscope, is considered substantially equivalent to legally marketed device of K171692, KCT, 21CFR 880.6850:

Instrument basket, for ENDOEYE

No reference devices were used in this submission.

2.4 Product Description

The instrument tray, for semi-rigid ureteroscope is specifically designed for enclosure of Olympus ureteroscopes and accessories during sterilization and storage of Olympus ureteroscopes and accessories after sterilization, as well as enclosure during transport within the reprocessing cycle. A loaded instrument tray cannot be used for automated cleaning of the contained devices.

The Olympus instrument tray is autoclavable and delivered in non-sterile condition to the customer. It is reusable and has to be reprocessed before first and each subsequent use according to defined reprocessing methods in the Instructions for Use.

2.5 Indications for Use

The instrument tray is intended to be used to enclose and protect one Olympus semi-rigid ureteroscope, models WA2UR11A, WA2UR12A, WA2UR13A, WA2UR14A, WA2UR21A, WA2UR22A, WA2UR23A, WA2UR31A, and WA2UR32A (K200369), and accessories during sterilization in a prevacuum steam sterilizer using the following parameters or cycles:

Prevacuum steam sterilization
- Exposure time at a temperature of 132 °C (269.6 °F:)
Wrapped instruments .....4 min.
Unwrapped non-porous instruments .....3 min.

- Exposure time at a temperature of 135 °C (275 °F:)
Wrapped instruments .....3 min.
Unwrapped non-porous instruments .....3 min.

- Drying time.....30 min.

After steam sterilization, let the instrument tray cool down at room temperature.
- Cool-down time.....30 min.

The instrument tray is also intended for the enclosure of Olympus semi-rigid ureteroscopes and accessories during transport and storage within the reprocessing cycle. The instrument tray is not compatible with flexible ureteroscopes.

The instrument tray is to be used in conjunction with a FDA cleared sterilization wrap. Maintenance of sterility depends on the sterilization wrap.

Worst case load:

The instrument tray containing a ureteroscope, attachments, light-guide cable, light-guide cable adapters, sealing caps and stopcocks must not exceed a weight of 3300 grams (7.27 lb) altogether.

2.6 Technological Characteristic Comparison with Predicate

Provided below is a technological comparison of the subject device with the predicate device.

Item of Comparison	*Subject Device, K203492*	*Predicate Device, K171692*	*Evaluation of Differences*
General technology	Perforated rigid enclosure designed to enclose Olympus telescopes and accessories while allowing for sufficient penetration of reprocessing agents.	Perforated rigid enclosure designed to enclose Olympus video telescopes and accessories while allowing for sufficient penetration of reprocessing agents.	**Same**
Indications for Use	The instrument tray is intended to be used to enclose and protect one Olympus semi-rigid ureteroscope, models WA2UR11A, WA2UR12A, WA2UR13A, WA2UR14A, WA2UR21A, WA2UR22A, WA2UR23A, WA2UR31A, and WA2UR32A (K200369), and accessories during sterilization in a prevacuum steam sterilizer using the following parameters or cycles: Prevacuum steam sterilization - Exposure time at a temperature of 132 °C (269.6 °F:) Wrapped instruments .....4 min.	The instrument basket is intended to be used to enclose and protect one Olympus video telescope for sterilization in a prevacuum steam sterilizer or STERRAD® sterilizer using the following parameters or cycles: • Prevacuum steam sterilization - Exposure time at a temperature of 132 °C (269.6 °F:) Wrapped instruments ..... 4 min. Immediate-use non-porous instruments ……..3 min. - Exposure time at a temperature of 135 °C (275 °F:) Wrapped instruments .....3 min. Immediate-use non-porous instruments ….....3 min.	**Similar**

Item of Comparison	*Subject Device, K203492*	*Predicate Device, K171692*	*Evaluation of Differences*
	Unwrapped non-porous instruments .....3 min. - Exposure time at a temperature of 135 °C (275 °F:) Wrapped instruments .....3 min. Unwrapped non-porous instruments .....3 min. - Drying time.....30 min. After steam sterilization, let the instrument tray cool down at room temperature. - Cool-down time.....30 min. The instrument tray is also intended for the enclosure of Olympus semi-rigid ureteroscopes and accessories during transport and storage within the reprocessing cycle. The instrument tray is not compatible with flexible ureteroscopes. The instrument tray is to be used in conjunction with a FDA cleared sterilization wrap. Maintenance of sterility depends on the sterilization wrap. Worst case load: The instrument tray containing a ureteroscope, attachments, light-guide cable, light-guide cable adapters, sealing caps	- Drying time .....30 min. After steam sterilization, let the instrument basket cool down at room temperature. - Cool-down time .....30 min. • STERRAD® sterilization - STERRAD® 100S cycle - STERRAD® 100NX™: standard cycle and express cycle The instrument basket is not intended to maintain sterility. It is intended to be used in conjunction with a 510K cleared sterilization wrap to maintain sterility of the enclosed Olympus video telescope and accessories. Validated worst-case load The instrument basket which is double-wrapped in a sterilization wrap with one enclosed Olympus video telescope and accessories must not exceed 8.708 lb (3950 g).	

Item of Comparison	*Subject Device, K203492*	*Predicate Device, K171692*	*Evaluation of Differences*
	and stopcocks must not exceed a weight of 3300 grams (7.27 lb) altogether.		
Intended to be reused	Yes	Yes	**Same**
Device Setup	Consists of base with lid (lid can be fastened by a latching mechanism)	Consists of base with lid, lid can be fastened by a latching mechanism	**Same**
Percentage of surface perforation	About 39%	About 72%	**Different**
Microbial barrier properties	To be used with FDA cleared sterilization wrap	To be used with FDA cleared sterilization wrap	**Same**
Toxicological properties	Under conditions of the study, the materials are non-cytotoxic	Under conditions of the study, the materials are non-cytotoxic	**Same**
Autoclavability (steam sterilization) of empty basket/tray	yes	yes	**Same**
Validated Drying time (steam sterilization)	30 minutes	30 minutes	**Same**
Material	Stainless steel, Silicone	Stainless steel, Silicone	**Same**

2.7 Summary of Non-clinical Testing

The following performance data were provided in support of the equivalence determination. All standards applied are FDA recognized international standards.

Name	*Purpose*	*Acceptance Criteria*	*Results*
ISO 10993-5:2009	Demonstration of biocompatibility for materials that contact the loaded devices	Non-cytotoxic under the conditions of the study	Pass
ISO 10993-12:2012	Chemical analysis, and sample preparation	Non-cytotoxic under the conditions of the study	Pass
Cleaning validation	Demonstration of the efficacy of the cleaning procedure	Visibly clean Residual protein content less than 3 microgram/cm2 Residual TOC less than 12 microgram/cm2	Pass

Name	*Purpose*	*Acceptance Criteria*	*Results*
Half-cycle sterilization validation	Demonstration of 6 log reduction of stearothermophilus Geobacillus under half cycle conditions	No viable growth	Pass
Verification of tray durability after repeated sterilization cycles	Demonstration of tray durability over 400 sterilization cycles	No visible degradation No corrosion Legibility of markings	Pass
Evaluation of residual moisture	Demonstrate adequate drying time	No visible condensation or pooling on the wrap and contents free of visible condensation	Pass

2.7.1 Applied standards

Standard No.	Standard Title	FDA-Recognition no + date
ISO 10993-1 Fourth Edition 2009	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process [Including: Technical Corrigendum 1 (2010)]	2-220 07/26/2016
ISO 10993-5 Third Edition 2009	Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity	2-245 12/23/2016
ISO 10993-12 Fourth Edition 2012	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials	2-191 07/26/2016
IEC 62366-1 Edition 1.0 2015-02	Medical devices - Part 1: Application of usability engineering to medical devices [Including CORRIGENDUM 1 (2016)]	5-114 12/23/2016
ANSI AAMI ST77 2013/(R)2018	Containment devices for reusable medical device sterilization	14-396 01/14/2019
ISO 14971 Second edition 2007	Medical devices - Application of risk management to medical devices	5-40 06/27/2016

Table 2.1: Applied standards

2.8 Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject Instrument tray, for semi-rigid ureteroscope, is as safe, as effective and performs as

well as or better than the legally marketed predicate device, Instrument basket, for ENDOEYE (K171692).