DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 2, 2018

Sheri L. Musgnung
Regulatory Affairs Manager
Olympus Corporation of the Americas
3500 Corporate Parkway
PO Box 610
Center Valley, PA 18034-0610

Re: K171692
Trade/Device Name: Instrument basket, for ENDOEYE
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: March 01, 2018
Received: March 05, 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.

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" (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.

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 yours,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory, Infection
Control, and Dental 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K171692

Device Name
Instrument basket, for ENDOEYE

Indications for Use *(Describe)*
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.

- 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).

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

510(k) Summary

K171692

1. General information

- Manufacturer/Holder: Olympus Winter & Ibe GmbH
  Kuehnstr. 61
  22045 Hamburg
  Germany
- Establishment Registration No.: 9610773
- Official Correspondent: Sheri L. Musgnung
  Regulatory Affairs
  Olympus Corporation of the Americas
  3500 Corporate Parkway
  PO Box 610
  Center Valley, PA 18034-0610
  Phone: 484-896-3147
  FAX: 484-896-7128
  Email: sheri.musgnung@olympus.com
  Establishment Registration No.: 2429304

Submission Date: March 29, 2018

2. Device identification

- Proprietary name: Instrument basket, for ENDOEYE
- Common name: Sterilization wrap containers, trays, cassettes & other accessories
- Regulation Number: 21 CFR 880.6850
- Regulation Description: Sterilization wrap
- Device Class: II
- Product Code: KCT
- Review Panel: General Hospital

3. Predicate device

K033222, Olympus Instrument Tray, for video telescopes

4. Description of device

The instrument basket, for ENDOEYE is specifically designed for enclosure of Olympus video telescopes and accessories during sterilization and storage of Olympus video telescopes and accessories after sterilization as well as enclosure during transport within the reprocessing cycle.

The Olympus instrument basket 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

5. Indications of use

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.

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).

5.1 Comparison of Indications for Use statement to the predicate:

The subject device has a similar intended Use as the legally-marketed Instrument tray, for EndoEYE cleared via K033222 (August 2, 2004) since both are sterilization trays. Also the predicate device and new Instrument basket, for ENDOEYE can undergo steam sterilization with the same enclosed devices. The main difference between the subject device and the predicate is that the new Instrument basket, for ENDOEYE can also be used during STERRAD® sterilization.

6. Comparison of technological characteristics

Item of Comparison	***Predicate Device***	***Subject Device***	***Comparison***
General technology	Perforated rigid enclosure designed to enclose Olympus video 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.	Identical
Intended to be reused	Yes	Yes	Identical
Design	Rigid containment device consisting of a base with lid which can be fastened by a latching mechanism. The device is perforated in order to enable reprocessing of enclosed medical devices held in	Rigid containment device consisting of a base with lid which can be fastened by a latching mechanism. The device is perforated in order to enable reprocessing of enclosed medical devices held in place by silicone	Identical

	place by silicone retainers.	retainers.	
Percentage of surface perforation	About 3.3%	About 72%	The increased surface perforation does not introduce any additional risks since the main characteristics (fit geometry trough design, base with closeable lid) remain identical.
Microbial barrier properties	To be used with FDA cleared sterilization wrap	To be used with FDA cleared sterilization wrap	Identical
Toxicological properties	Materials are biocompatible	Materials are biocompatible	Identical
Material	Thermoplastic, silicone	Stainless steel, silicone	The materials used are different. All materials used in the subject device have been validated to be biocompatible and verified to be compatible with the intended reprocessing methods. Therefore, the use of different materials in the subject device does not raise different questions of safety and effectiveness compared to the predicate device.
Autoclavability (steam sterilization) of empty basket/tray	yes	yes	Identical
STERRAD® sterilization **(gas plasma) of empty basket/tray**	no	STERRAD® 100S cycle STERRAD® 100NX™: standard cycle and express cycle	STERRAD sterilization was added as an additional sterilization option for the subject device

Drying time (steam sterilization)	15-30 minutes	30 minutes	Identical

7. Performance Data

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

Performance tests were carried out to ensure that the system functions as intended and meets design specifications. The following performance tests and usability studies were conducted:

Biocompatibility testing

The biocompatibility evaluation for the subject device was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995.
The testing included the following tests:

- Biological Safety – toxicology: AAMI ANSI ISO 10993-1:2009; Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process
- Cytotoxicity: AAMI ANSI ISO 10993-5:2009; Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- Chemical Analysis: AAMI ANSI ISO 10993-12:2012; Biological evaluation of medical devices - Part 12: Sample Preparation and Reference Materials

Performance Bench Testing

The instrument basket is specifically designed for enclosure of Olympus video telescopes and accessories during sterilization and storage of Olympus video telescopes and accessories after sterilization process.

Its main performance characteristics are:

- The mechanical protection of the enclosed video telescopes ensured by adaptive holding retainers and closeable basket design
- Enabling automated cleaning/disinfection of loaded video telescopes (validated combinations only as outlined in the respective device IFU's)
- Enabling use with sterilization wrap (maintaining sterility is secured by the sterilization wrap which is not part of this submission)
- Enabling sterilization of loaded video telescopes (validated combinations only as outlined in the respective device IFU's)

To outline that these performance characteristics have been met the submission contains the respective validations, tests and an outline of the design as required by the recognized standard AAMI / ANSI ST77:2013, containment devices for reusable medical device sterilization. (Sterility) (recognition number: 14-396) assigned to the product code KCT.

The following standards have been applied to the Instrument Basket:

Rec. No.	Standard
2-220	ISO 10993-1:2009
2-245	ISO 10993-5:2009
2-191	ISO 10993-12:2012
5-40	ISO 14971:2007
14-396	AAMI ANSI ST77:2013
5-96	AAMI ANSI IEC 62366-1:2015

For the above mentioned ISO standards, identical DIN EN ISO standards have been used by the recognized test laboratories.

8 Conclusion

Based on the intended use, technological characteristics, performance data, and nonclinical tests performed, subject Instrument basket, for ENDOEYE is substantially equivalent to, and is as safe and as effective as, the legally marketed predicate device, Olympus sterilization trays cleared under K033222 under regulation 21 CFR 880.6850, product code KCT.