



Food and Drug Administration
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April 29, 2015

Olympus Winter & Ibe GmbH
Ms. Sheri L. Musgnung
Olympus Corporation of the Americas
3500 Corporate Parkway
PO Box 610
Center Valley, Pennsylvania 18034

Re: K150633

Trade/Device Name: "ULTRA" Telescopes
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ, NMH, HET
Dated: March 11, 2015
Received: March 11, 2015

Dear Ms. 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" (21CFR 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,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K150633

Device Name

"ULTRA" Telescopes

Indications for Use (Describe)

These endoscopes are intended to be used for endoscopy and endoscopic surgery within the thoracic and peritoneal cavities including the female reproductive organs. The device is also indicated for visualization of transanal and transvaginal applications.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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 of Safety and Effectiveness

March 11, 2015

1. General information

- Manufacturer/Holder Olympus Winter & Ibe GmbH
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22045 Hamburg
Germany
- Establishment Registration No.: 9610773
- Official Correspondent: Sheri L. Musgnung
Regulatory Affairs & Quality Assurance
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FAX: 484-896-7128
Email: sheri.musgnung@olympus.com
Establishment Registration No.: 2429304

2. Device identification

- Proprietary name: "ULTRA" Telescopes
- Common name: Laparoscopes
- Regulation Number: 21 CFR 876.1500
21 CFR 884.1720
- Regulation Description: Endoscope and Accessories
Gynecologic laparoscope and
accessories
- Device Class: II
- Product Code: GCJ / NMH / HET
- Review Panel: General & Plastic Surgery
Obstetrics/Gynecology

3. Predicate device

K923982, Olympus OES Laparoscopy System

4. Description of device

The "ULTRA" Telescopes are rigid endoscopes. An image relay system of rod lenses transmits the endoscopic image. A bundle of optical fibers transmits light from an external light source to illuminate the endoscopic image.

The "ULTRA" Telescopes are delivered non-sterile. They are reusable and fully autoclavable. Before first and each subsequent use the device must be inspected and reprocessed according to defined reprocessing methods in the Instructions for Use.

The "ULTRA" Telescopes will be marketed as individual telescopes.

The "ULTRA" Telescopes are available in two different diameters (5.4 mm and 10 mm) with three different directions of view (0°, 30°, 45°) each to allow use for various applications in accordance with the intended use as submitted with this 510(k).

Model No.	Model name
WA4KL100	Telescope "ULTRA", 10 mm, 0°
WA4KL130	Telescope "ULTRA", 10 mm, 30°
WA4KL145	Telescope "ULTRA", 10 mm, 45°
WA4KL500	Telescope "ULTRA", 5.4 mm, 0°
WA4KL530	Telescope "ULTRA", 5.4 mm, 30°
WA4KL545	Telescope "ULTRA", 5.4 mm, 45°

5. Indications of use

These endoscopes are intended to be used for endoscopy and endoscopic surgery within the thoracic and peritoneal cavities including the female reproductive organs. The device is also indicated for visualization of transanal and transvaginal applications.

6. Comparison of Technological characteristics

The subject and predicate devices are based on the same technological principle with the same elements:

- Rigid endoscopes consisting of insertion tube, rod-lens and light-guide system, connector and eyepiece cup
- Inserted into natural and surgically opened body spaces
- A bundle of optical fibers transmits light from an external light source to illuminate the endoscopic image.
- The image relay system of rod lenses transmits the endoscopic image
- Identical, respectively similar outer diameters
- Telescopes are used with standardized trocars
- Identical Direction of Views (DOVs)
- The Field of View (FOV) of subject devices is wider (Ø Factor 1.2)

- Maximum working length of subject device is minimally longer
- The same materials in patient contact are used in predicate and subject device

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

Electrical safety and electromagnetic compatibility (EMC)

Electrical Safety was tested according to AAMI/ANSI ES 60601-1:2005 and C1:2009 and A2:2010; Medical Electrical Equipment - Part 1.1 General requirements for safety and essential performance.

Electromagnetic compatibility (EMC) is not applicable. The devices are not electrically powered and are just used with light from a light source.

Thermal Safety

Tested according to IEC 60601-2-18:2009, Medical electrical equipment - Part 2-18: 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 as well as in accordance with the guidance document "Hysteroscopes and Gynecology Laparoscopes - Submission Guidance for a 510(k)".

Performance Testing Bench

Conducted tests cover optical and mechanical performance testing, shipping tests, tests related to the expected service life and testing of the illumination system. Additionally, design validation/usability tests were conducted.

The following standards have been applied to the “ULTRA” Telescopes:

<u>Rec. No.</u>	<u>Standard</u>
9-61	IEC 60601-2-18:2009; 3 rd Ed.
9-83	ISO 8600-1:2013
9-84	ISO 8600-3:1997 + AM1(2003)
9-94	ISO 8600-4:2014
9-39	ISO 8600-5:2005
9-40	ISO 8600-6:2005
5-40	ISO 14971:2007
19-4	AAMI / ANSI ES60601-1:2005/(R)2012 and A1:2012,, c1:2009/(r)2012 and a2:2010/(r)2012 (IEC 60601-1:2005, mod).
5-89	IEC 60601-1-6:2013
2-156	AAMI ANSI ISO 10993-1: 2009
2-153	AAMI ANSI ISO 10993-5: 2009
2-198	AAMI ANSI ISO 10993-12: 2012
14-333	ISO 17665-1:2006

8 Conclusions

The performance data support the safety of the device and demonstrate that the subject devices comply with the intended use as specified.

In summary, we believe the “ULTRA” Telescopes are substantially equivalent to the predicate devices with respect to the general design approach, function, and the intended use. The “ULTRA” Telescopes raise no new concerns of safety or effectiveness compared to the predicate devices.