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

November 24, 2015

Olympus Winter & Ibe GmbH
% Daphney Germain-Kolawole
Manager, Regulatory Affairs
Olympus Corporation of The Americas
3500 Corporate Parkway
Center Valley, PA 18034

Re: K151191
Trade/Device Name: OES Elite Telescopes, Protective Tube
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FBP, FGC, HIH
Dated: October 14, 2015
Received: October 15, 2015

Dear Daphney Germain-Kolawole,

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,

Herbert P. Lerner -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)*
K151191

Device Name
OES ELITE Telescopes, Protective Tube

Indications for Use *(Describe)*
The OES Elite Telescopes are indicated to provide the user with the means for visualizing diagnostic and therapeutic surgical procedures. The device is intended for use in general urological and gynecological surgery through the minimally invasive approach, by utilizing natural orifices to access the surgical site.

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 of Safety and Effectiveness

November 24, 2015

1. General information

- Manufacturer/Holder: Olympus Winter & Ibe GmbH
  Kuehnstr. 61
  22045 Hamburg
  Germany
- Establishment Registration No.: 9610773
- Official Correspondent: Daphney Germain-Kolawole
  Regulatory Affairs & Quality Assurance
  Olympus Corporation of the Americas
  3500 Corporate Parkway
  PO Box 610
  Center Valley, PA 18034-0610
  Phone: 484-896-5691
  FAX: 484-896-7128
  Email: daphney.germain-kolawole@olympus.com
  Establishment Registration No.: 2429304

2. Device identification

- Device Trade Name: OES ELITE Telescopes, Protective Tube
- Device Classification Name: Telescope, Rigid, Endoscopic
- Regulation Description: Endoscope and accessories
- Product Code: FBP
- Subsequent Product Codes: FGC, HIH
- Regulation Number: 21 CFR 876.1500
- 21 CFR 884.1690
- Review Panel: Gastroenterology/Urology
- Obstetrics/Gynecology
- Device Class: 2

3. Predicate device

K923982, Olympus OES Laparoscopy System

4. Description of device

The OES ELITE 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 OES ELITE 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 OES ELITE Telescopes will be marketed as individual telescopes.

The OES ELITE Telescopes are available in 4 mm diameters with four different directions of view (0°, 12°, 30°, 70°) each to allow use for various applications in accordance with the intended use as submitted with this 510(k).

Model No.	Model name
WA2T400A	OES ELITE Telescope, 4mm, 0°
WA2T412A	OES ELITE Telescope, 4mm, 12°
WA2T430A	OES ELITE Telescope, 4mm, 30°
WA2T470A	OES ELITE Telescope, 4mm, 70°
WA2T43WA	OES ELITE Telescope, 4mm, 30°

The OES ELITE Telescopes will be delivered with a protective tube WA2P400A which is subject to this 510(k) submission

5. Indications of use

The OES Elite Telescopes are indicated to provide the user with the means for visualizing diagnostic and therapeutic surgical procedures. The device is intended for use in general urological and gynecological surgery through the minimally invasive approach, by utilizing natural orifices to access the surgical site.

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.
- OES ELITE Telescopes are inserted only via natural body orifices. The predicate device additionally permitted surgical access.

- 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.
- Outer diameter reduced by 1mm.
- Directions of Views (DOVs) adjusted. Predicate device from 0°, 12°, 45°. Subject device from 0°, 12°, 30°, 70°.
- The 5mm telescopes of the predicate device had a field of view (FOW) of 70.5°. The Subject device now offers two FOV´s 60° and 90°.
- Maximum working length of the subject device is minimally reduced (10mm)
- The same materials in patient contact are used in the predicate and subject devices.

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
- Biological Evaluation in accordance with AAMI ANSI ISO 10993-1: 2009

Electrical safety and electromagnetic compatibility (EMC)

Electrical Safety was tested according to AAMI / ANSI ES60601-1:2005/(R)2012; 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 OES ELITE Telescopes:

Rec. No.	Standard
9-61	IEC 60601-2-18:2009; 3rd 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 OES ELITE Telescopes are substantially equivalent to the predicate devices with respect to the general design approach, function, and the intended use. The OES ELITE Telescopes raise no new concerns of safety or effectiveness compared to the predicate devices.