December 22, 2021

Olympus Winter & Ibe GmbH
% Jonathan Gilbert
Regulatory Affairs Consultant for OCA
Olympus Corporation of the Americas (OCA)
3500 Corporate Parkway
Center Valley, PA 18034

Re: K213207
Trade/Device Name: Sheath and Stopcock Accessory
Regulation Number: 21 CFR§ 884.1690
Regulation Name: Hysteroscope and Accessories
Regulatory Class: II
Product Code: HIH
Dated: September 28, 2021
Received: September 29, 2021

Dear Jonathan Gilbert:

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,

for
Jason R. Roberts, Ph.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213207

Device Name
Sheath and Stopcock Accessory

Indications for Use *(Describe)*
Sheath with integrated stopcocks are used in conjunction with a hysteroscope to permit direct viewing of the cervical canal and the uterine cavity to perform diagnostic and surgical procedures.

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.

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"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

1 General Information

- **Applicant** Olympus Winter & Ibe GmbH
  Kuehnstr. 61 * 22045 Hamburg * Germany
  Establishment Registration No: 9610773
- **Official Correspondent** Jon Gilbert fbo Christina Flores
  Manager, Regulatory Affairs
  800 West Park Drive
  Westborough, MA 01581
  Email: Christina.Flores@olympus-osta.com
  Phone: (508) 808-3341
  Establishment Registration No.: 3003790304
- **Manufacturer** Olympus Winter and Ibe GmbH
  Kuehnstr. 61 * 22045 Hamburg * Germany
  Establishment Registration No.: 9610773

2 Device Identification

- **Device Trade Name:** Sheath and Stopcock Accessory
- **Common Name:** Hysteroscope (And Accessories)
- **Regulation Number:** 21 CFR 884.1690
- **Regulation Name:** Hysteroscope and accessories
- **Regulatory Class:** II
- **Product Code:** HIH (Hysteroscope and accessories)

3 Predicate Device

The Sheath and stopcock accessory is considered substantially equivalent to:

Table 1: Predicate device

Predicate device	Manufacturer	510(k) No
TROCARS, CANNULAE, SHEATHS, OBTURATORS	Karl Storz Endoskop GmbH	K943713

The predicate device has not been subject to a design-related recall.

4 Device Description

The subject device is a reusable sheath (Part WA47777A) and stopcock (Part WA47778A), provided non-sterile and labeled for reprocessing via cleaning and steam sterilization.

The sheath is a rigid instrument made from stainless steel. The sheath has a working length of 206.7 ± 0.15 mm. The sheath has a single lumen shaped to allow for both, insertion of one 3 mm hysteroscope as well as a 5 Fr instrument channel for the instrument and irrigation inflow. There are three ports, one for irrigation, one for instruments, and one for the hysteroscope. There is no outflow channel for the irrigation fluid; the irrigation fluid flows out between the sheath and the cervix channel. A hysteroscope can be inserted into the hysteroscope channel of the sheath from the proximal end to provide an endoscopic image during the procedure. The endoscopic image can be viewed using the ocular or by connecting a compatible camera head. Compatible surgical instruments can be inserted into the instrument channel of the sheath. The irrigation stopcock made from stainless steel and polyether ether ketone (PEEK) can be used to control the inflow of the irrigation fluid. The instrument stopcock controls the passage of the surgical instruments.

5 Indications for Use

The subject device has the following indications for use:

> Sheath with integrated stopcocks are used in conjunction with a hysteroscope to permit direct viewing of the cervical canal and the uterine cavity to perform diagnostic and surgical procedures.

The subject and predicate device have the same intended use, to allow medical equipment to be delivered to procedural sites. There are no intended use concerns with the subject device.

6 Comparison of Technological Characteristics

The technological characteristics of the subject device are considered substantially equivalent to the predicate and reference device.

6.1 Comparison of subject and predicate device

The subject and predicate device share the following characteristics:

- Same general indications for use

- Similar cross-sectional and shaft design
- Same patient contacting materials
- Comparative testing showed that the subject device has equivalent performance in respect to the irrigation fluid outflow

The following differences to the predicate device exist:

- Subject device does not incorporate an inner sheath
- The working length and lumen diameters are different
- Subject device has no irrigation holes at distal end, since irrigation fluid outflow is not inside the shaft between inner and outer sheath

As stated above, the subject and predicate devices have similar design characteristics and show comparable performance. The differences in technological characteristics do not raise different questions of safety and effectiveness.

7 Performance Data

The following performance data was provided to support a determination of substantial equivalence.

7.1 Biocompatibility testing

The patient contacting materials of the sheath and stopcock have been tested for biocompatibility in compliance with the FDA guidance document *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"*, dated September 2020:

- Cytotoxicity according to ISO 10993-5:2009;
- Sensitization according to ISO 10993-10:2010; and
- Intracutaneous Irritation according to ISO 10993-10:2010

The results showed that the subject device was non-cytotoxic, non-sensitizing, and non-irritating.

7.2 Performance Testing Bench

To demonstrate substantial equivalence and address mechanical performance as recommended in the FDA guidance document *"Hysteroscopes and Gynecologic Laparoscopes"*, dated March 7, 1996, mechanical resistance of the inflow interface, scope interface and instrument interface, resistance of the sheath tube, resistance of the supporting ring of the optic guide plate, resistance against repeated assembly/disassembly, and irrigation inflow and outflow were compared during comparative validation testing.

These bench tests demonstrated that comparable flow could be achieved during operation and addressed the mechanical performance recommendations outlined in the guidance.

7.3 Electrical and Thermal Safety

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

The subject device was evaluated for thermal and electrical safety, to demonstrate the subject device is not a heat hazard and compatible with energized devices, according to the following standards:

- Heat hazard assessment per AAMI/ANSI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012;
- Safety with electrocautery devices per AAMI/ANSI IEC 60601-2-2:2017; and
- Basic endoscopic safety per IEC 60601-2-18:2009

7.4 Reprocessing/ Sterilization

Reprocessing instructions and method validation testing for the subject device was conducted and documentation provided as recommended by the FDA guidance document *"Reprocessing Medical Devices in Health Care Setting: Validation Methods and Labeling"*, dated March 17, 2015.

8 Conclusion

The performance data summarized above demonstrate that the subject device is as safe and effective as the predicate device. The subject device is substantially equivalent to the predicate device.