August 3, 2021

Olympus Winter & Ibe GmbH
% Christina Flores
Manager, Regulatory Affairs
Olympus Surgical Technologies America
118 Turnpike Road
Southborough, Massachusetts 01772

Re: K210651
Trade/Device Name: Resection Electrodes with HF cable
Regulation Number: 21 CFR 884.1690
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulatory Class: II
Product Code: FAS, HIH, FJL
Dated: July 16, 2021
Received: July 20, 2021

Dear Christina Flores:

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,

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)*

K210651

Device Name

Resection Electrodes with HF cable (WA22702S, WA22703S, WA22705S, WA22706S, WA22707S, WA22721S, WA22723S, WA22732S, WA22737S, WA22738S, WA22739S, WA22751S, WA22755S, WA22760S, WA22766S, WA22740S, WA22741S, WA22742S, WA22743S, WA22744S)

Indications for Use *(Describe)*

Electrodes with HF-cable are part of a resectoscope system for endoscopic diagnosis and treatment in urological applications: Cutting, ablation, resection, vaporization and coagulation with HF current.

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
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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."

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)*

K210651

Device Name

Resection Electrodes with HF cable (WA47705S, WA47706S, WA47707S, WA47721S, WA47723S, WA47732S, WA47737S, WA47738S, WA47739S, WA47751S, WA47755S, WA47760S, WA47766S, WA47740S, WA47741S, WA47742S, WA47743S, WA47744S)

Indications for Use *(Describe)*

Electrodes with HF-cable are part of a resectoscope system for endoscopic diagnosis and treatment in gynecological applications.
The general indications include transcervical resection, vaporization, ablation, cutting and coagulation of tissue in the uterus in conductive irrigation fluid as part of a resectoscope system.

Specific indications:
- transcervical diagnosis and treatment (resection, vaporization, ablation, biopsy, cutting and coagulation) of intrauterine myomas, intrauterine polyps, synechias and endometrium (TCRis)
- lysis of intrauterine septa
- endometrial ablation

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)

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510(k) Summary

1. Submitter Information

Submitter Address: Olympus Winter & Ibe GmbH
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22045 Hamburg
Germany

Contact person: Christina Flores, RAC
Regulatory Affairs Manager
Olympus Surgical Technologies America
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Phone: (508) 808-3341
Email: christina.flores@olympus.com

Date prepared: August 3, 2021

2. Device Information

Trade Name:	Resection Electrodes with HF cable
Common Name:	Electrode, Electrosurgical, active, urological
Regulation Number:	876.4300
Classification	Endoscopic electrosurgical unit and accessories
Device Class:	II
Product Code:	FAS / HIH / FJL
Review Panel:	Gastroenterology / Urology / Obstetrics / Gynecology

Model numbers:

WA22702S, WA22703S, WA22705S, WA22706S, WA22707S, WA22721S, WA22723S, WA22732S, WA22737S, WA22738S, WA22739S, WA22751S, WA22755S, WA22760S, WA22766S, WA22740S, WA22741S, WA22742S, WA22743S, WA22744S

WA47705S, WA47706S, WA47707S, WA47721S, WA47723S, WA47732S, WA47737S, WA47738S, WA47739S, WA47751S, WA47755S, WA47760S, WA47766S, WA47740S, WA47741S, WA47742S, WA47743S, WA47744S

3. Predicate Devices

The predicate device was chosen from the following predicate 510(k):

510(k) No.	Name	Predicate Model No.	Product code / Reg No.
K171965	Resection Electrodes with HF cable	WA22702S, WA22703S, WA22705S, WA22706S, WA22707S, WA22721S, WA22723S, WA22732S, WA22737S, WA22738S, WA22739S, WA22751S, WA22755S, WA22760S, WA22766S, WA22740S, WA22741S, WA22742S, WA22743S, WA22744S, WA47705S, WA47706S, WA47707S, WA47721S, WA47723S, WA47732S, WA47737S, WA47738S, WA47739S, WA47751S, WA47755S, WA47760S, WA47766S, WA47740S, WA47741S, WA47742S, WA47743S, WA47744S	FAS / 876.4300 FJL / 876.1500 HIH / 884.1690

These predicates have not been subject to a design-related recall.

4. Product Description

The Olympus Resection Electrodes with HF cable that are subject to this submission are for application in saline. Depending on the characteristics of electrical current, which is provided by the electrosurgical generator, electrosurgery can be used for coagulation, vaporization and cutting.

The subject HF-Resection Electrodes consist of an active tip, PTFE color code identification, an insulator between the electrode and electrode tube, a guiding tube, telescope clip and arm (shaft). The accompanying HF cables consist of two lantern plugs on the instrument side and one generator plug on the generator side.

The design and dimensions of the electrodes vary to accommodate various procedural conditions. The active tips of the various electrodes may consist of loops, bands, rollers, needles or buttons. The electrodes have a shaft diameter of 24 Fr, range in length from 261.8-336.7mm, and range in tip angle from 12° - 30° tips. The design of the HF cable plugs fits Olympus electrosurgical generators with Universal Socket.

All subject Resection Electrodes are **single-use** electrodes and are delivered **sterile**. All subject Resection Electrodes are provided with a **single-use**, **sterile** cable to connect the electrode to the generator.

5. Indications for Use

Resection Electrodes with HF cable for use in Urology
Article no.: WA22702S, WA22703S, WA22705S, WA22706S, WA22707S, WA22721S, WA22723S, WA22732S, WA22737S, WA22738S, WA22739S, WA22751S, WA22755S, WA22760S, WA22766S, WA22740S, WA22741S, WA22742S, WA22743S, WA22744S

Electrodes with HF-cable are part of a resectoscope system for endoscopic diagnosis and treatment in urological applications: Cutting, ablation, resection, vaporization and coagulation with HF current.

Resection Electrodes with HF cable for use in Gynecology
Article no.: WA47705S, WA47706S, WA47707S, WA47721S, WA47723S, WA47732S, WA47737S, WA47738S, WA47739S, WA47751S, WA47755S, WA47760S, WA47766S, WA47740S, WA47741S, WA47742S, WA47743S, WA47744S

Electrodes with HF-cable are part of a resectoscope system for endoscopic diagnosis and treatment in gynecological applications.

The general indications include transcervical resection, vaporization, ablation, cutting and coagulation of tissue in the uterus in conductive irrigation fluid as part of a resectoscope system.

Specific indications:

- transcervical diagnosis and treatment (resection, vaporization, ablation, biopsy, cutting and coagulation) of intrauterine myomas, intrauterine polyps, synechias and endometrium (TCRis)
- lysis of intrauterine septa
- endometrial ablation

The subject and predicate devices have the same indications for use statements.

6. Comparison of Technological characteristics

The following table compares the technological characteristics of the subject and predicate devices:

Device & Predicate Device(s):	K210651	K171965
Indication (anatomical site)	Gynecological and Urological	Gynecological and Urological
Mode of ablation	Bipolar (resection in saline)	Bipolar (resection in saline)
Irrigation solution	Saline	Saline
Length	261.8 – 336.7 mm	261.8 – 336.7 mm
Compatible scope shaft diameter	24 Fr	24 Fr
Electrode Active tip shapes	Loop, band, needle, roller, button	Loop, band, needle, roller, button
Electrode Active tip designs	12° - 30° angles	12° - 30° angles
Patient Contact Materials	stainless steel, elastosil (glue), ceramic, loctite 4303 (glue), PTFE, PtIr, tungsten	Stainless steel, Al_2O_3, PTFE (colors), PtIr
Stabilizing tube diameter	4.1 mm	4.1 mm
Sterilization and Packaging Materials	Provided sterile (EtO), Tyvek/Blister PET	Provided sterile (EtO), Tyvek/Blister PET
HF Cables packaged with the subject device	Yes	Yes
Shelf life	3 years	3 years
Compatible generator(s)	Current Olympus electrosurgical generators with UNIVERSAL socket [ESG-400 (K141225 and K203682), ESG-410 (K203277)] as well as future ESG-generations with UNIVERSAL socket	ESG-400 (K141225 and pending K203682)

At a high level, the subject and predicate devices are based on the same technological principle with the same elements:

- Resection electrodes consisting of an active (distal) tip, PTFE color code identification at the distal and proximal ends, an insulator between the electrode and electrode tube, a stabilizing (guiding) tube, and arm (shaft)
- HF cables consisting of two lantern plugs on the instrument side and one generator plug on the generator side
- Used in combination with a resectoscope system
- Like the predicate electrodes, the subject device resection electrode series features loops, bands, needles, rollers, and a button as active tip shapes
- Resection electrodes utilizing ablation or for resection in saline (dependent on model)
- Respectively identical outer dimensions
- Design changes of the electrodes and cables are minor and do not negatively impact safety or effectiveness of the subject devices
- The same or similar materials in patient contact are used in predicate and subject device and have all been successfully tested for biocompatibility.

As stated above, the subject and predicate devices have similar design characteristics and performance specifications, with the exception of the compatibility to the Olympus electrosurgical generators with UNIVERSAL socket. These minor differences, however, do not raise different questions of safety or effectiveness. As demonstrated in the non-clinical testing (e.g., electrical safety, sterilization validation, and package integrity), the different technological characteristics do not affect the safety and effectiveness of the subject devices.

7. Summary of Non-Clinical Performance Testing

The following tests were conducted to demonstrate the compatibility to Olympus HF generators that have UNIVERSAL socket to the instructions for use of the resection electrodes:

Mechanical performance:

- Mechanical compatibility
- Detaching force of electrode
- Lifetime connection/disconnection of the electrodes
- Compression and tension between guiding sheets and contact part
- Detaching force of the cable from ESG410

Resection/Coagulation performance:

- Duration of single activation in combination with a HF generator

Transport tests:

- Communication with a HF generator
- Electrode pull back to proximal stop

In addition, tests to evaluate manual assembly of the system and visual inspection of the generator display were conducted.

Electrical Safety was tested according to the following standards:

AAMI/ANSI ES 60601-1:2005 + A1:2012, C1:2009 and A2:2010	Medical Electrical Equipment - Part 1.1 General requirements for safety and essential performance.
AAMI/ANSI/IEC 60601-2-2 2017	Medical Electrical Equipment - Part 2-2: Particular Requirements for the Basic Safety And Essential Performance of High Frequency Surgical Equipment and High Frequency Surgical Accessories
IEC 60601-2-18:2009	Medical electrical equipment - Part 2-18: Medical Electrical Equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment.

Sterilization is performed according to ISO 11135:2014 and packaging conforms with ISO 11607-1: 2019. The EtO sterilization cycle has been validated.

A sterility assurance level (SAL) of 10^{-6} was reached during validation and will be used for routine sterilization in compliance with regulations in force for sterile medical devices.

The EtO residuals are within the limits after tunnel degassing time.

The subject device passed the simulated shipping distribution and associated packaging integrity testing conducted per ASTM D4169:2016, ASTM F88, ASTM F1929, and ASTM F2096.

The biocompatibility was evaluated in accordance with ISO-10993, including cytotoxicity (ISO 10993-5:2009), sensitization (ISO 10993-10:2010), irritation (ISO 10993-10:2010), acute systemic toxicity (ISO10993-11:2017), and material-mediated pyrogenicity (ISO10993-11:2017).

8. Conclusion

The performance data support the safety and effectiveness of the subject device and demonstrate that the subject device is substantially equivalent to the predicate device.

In conclusion, the Resection Electrodes with HF cable are substantially equivalent to the predicate devices.