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

September 6, 2016

Olympus Winter & Ibe GmbH
% Dolan Mills
Sr. Specialist, Regulatory Affairs
Gyrus ACMI, Inc.
136 Turnpike Road
Southborough, MA 01772

Re: K161600
Trade/Device Name: Resection Electrodes (model numbers WA47505S, WA47506S, WA47507S, WA47540S, WA47551S, WA47555S, WA47560S, WA47566S)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: JOS, HIH
Dated: June 8, 2016
Received: June 9, 2016

Dear Dolan Mills:

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,

Joyce M. Whang -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)*
K161600

Device Name
Resection Electrodes (model numbers WA47505S, WA47506S, WA47507S, WA47540S, WA47551S, WA47555S, WA47560S, WA47566S

Indications for Use *(Describe)*

Electrodes 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 saline irrigation fluid.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary of Safety and Effectiveness
June 8, 2016

1. General Information

Manufacturer: Olympus Winter & Ibe GmbH
Kuehnstr. 61
22045 Hamburg
Germany

Establishment Registration No.: 9610773

Official Correspondent: Dolan Mills
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Establishment Registration No.: 3003790304

2. Device Identification

Common Name:	Electrode, Electrosurgical / Hysteroscope (and accessories)
Regulation Number:	878.4400 / 884.1690
Classification	Electrosurgical cutting and coagulation device and accessories / Hysteroscope and accessories
Device Class:	II
Product Code:	JOS / HIH
Review Panel:	General & Plastic Surgery / Obstetrics/Gynecology
Proprietary/Trade Name:	Resection Electrodes
Model numbers:	WA47505S, WA47506S, WA47507S, WA47540S, WA47551S, WA47555S, WA47560S, WA47566S

3. Predicate Devices

The subject devices have been previously cleared for urological indications under K152092 (product codes FAS / FJL).

The predicate devices have not been subject to a design-related recall.

No reference devices were used in this submission.

4. Product Description

The Olympus Resection Electrodes 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 design and dimensions of the electrodes vary to accommodate various procedural conditions. The active tips of the various electrodes may consist of loops, rollers, needles or buttons.

All subject Resection Electrodes are **single-use** electrodes and are delivered **sterile** and are used in combination with a reusable HF cable (the HF cable is not subject to this submission).

5. Indications for Use

Electrodes 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 saline irrigation fluid.

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

Although the subject and predicate devices have different indications for use statements, the intended use is the same. The subject device is indicated for gynecologic applications while the predicate device is indicated for urological indications. However, when the decision-making criteria specified in the FDA

guidance document, "General/Specific Intended Use," (issued November 4, 1998) are applied, the subject device indications are determined to fall within the scope of the intended use of the predicate device. The specific gynecology indications of the subject device do not represent a different intended use since there is an extensive knowledge base regarding the use of bipolar electrosurgery for gynecological applications, including the disease states listed in the specific gynecologic indications. Therefore, the intended use comparison supports substantial equivalence.

6. Comparison of Technological characteristics

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

- Identical in design
- Used in combination with a resectoscope system (identical to predicate)
- Like the predicate electrodes, the subject device resection electrode series features loops, needles, rollers, and buttons as active tip shapes
- Utilizing resection in saline as mode of ablation (identical to predicate)

7. Performance Data

The subject device is identical in design and manufacturing to the predicate device (K152092). Therefore, the current submission relies on performance testing previously reviewed and deemed acceptable in K152092.

8. Sterilization and Shelf Life

Sterilization is performed according to ISO 11135 and packaging conforms with ISO 11607-1. Since the subject device is identical in design and manufacturing to the predicate device, the current submission relies on sterilization and packaging validation testing previously reviewed and deemed acceptable in K152092.

9. Conclusion

The subject device is substantially equivalent to the predicate device.