JUN 20 2012

510(k) Summary of Safety and Effectiveness

June 20, 2012

1. General Information:

Applicant:

Olympus Winter & Ibe GmbH
Kuehnstrasse 61
22045 Hamburg, Germany
Registration Number: 9610773
Owner/Operator Number: 8010313

Official Correspondent:

Sheri L. Musgnung
Regulatory Affairs & Quality Assurance
Olympus America Inc.
3500 Corporate Parkway, PO Box 610
Center Valley, PA 18034-0610
Phone: 484-896-3147
Facsimile: (484) 896-7128
Email: Sheri.Musgnung@Olympus.com
Registration No: 2429304

Manufacturer:

Olympus Winter & Ibe GmbH
Kuehnstrasse 61
22045 Hamburg, Germany
Registration Number: 9610773

2. Device(s) Identification:

Device Trade Name: Electrosurgical Resection and Vaporization Electrode Series

Common Name: Electrosurgical Cutting & Coagulation Device & Accessories Electrode, Electrosurgical, Active, Urological

Classification of the device:

Device Classification Name: Electrosurgical, cutting & coagulation & accessories
Endoscopic electrosurgical unit and accessories
Resectoscope
Resectoscope Working Element

Product Code: FAS, GEI, FJL, FDC

Device Classification No.: Part 876.4400, 21 CFR 876.4300, 21 CFR 876.1500

Panel: General & Plastic Surgery / Gastroenterology and Urology

Regulatory Status: Class II

3. Legally Marketed Predicate Device to which Substantial Equivalence is Claimed:

Device Trade Name:	HF Electrosurgical Resection and Vaporization Electrode Series
Applicant:	Olympus Winter & Ibe GmbH
510(k) No.:	K100275
Model Nos.:	WA22301D, WA22302D, WA22503D, WA22305D, WA22306D, WA22507D, WA22537D, WA22521C, WA22523C, WA22331D, WA22332D, WA22538C, WA22539D, WA22351C, WA22438C, WA22355C, WA 22351A, WA22355A, WA22558C, WA22557C

4. Device Description:

The HF-Resection Electrodes and HF Resection Button Electrode for Plasma Vaporization 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, bands, rollers, needles or buttons.

The system includes Electrodes, working elements, and an HF bipolar cable that can be connected to an electrical surgical unit.

HF Resection Electrodes (K100275) can now be used with the newly compatible electrosurgical generator, the ESG-400 (K103032). For the HF Resection Electrodes to be used with the ESG-400, an additional HF cable is needed (WA00014A). The WA00014A bipolar reusable cable is an electrosurgical accessory designed to transfer electrosurgical power to electrosurgical working elements from the electrosurgical generator ESG-400 (K103032). The cable is designed to connect the working elements WA22366A and WA22367A (K100275).

5. Indications for Use:

The HF-Resection Electrodes are a bipolar instrument series designed and intended for use in endoscopic urological surgical procedures involving the resection, ablation or removal of soft tissue and where hemostasis is required. The specific urological indications include use in the prostate, bladder and bladder neck. The procedures for which the devices can be used are transurethral resection in saline (TURis), transurethral prostatectomy, transurethral resection of the prostate (TURP) for benign prostatic hyperplasia, transurethral incision of the prostate (TUIP) or bladder neck, transurethral resection of bladder tumors (TURBT) and cystodiathermy. These devices are intended to be used in an irrigated environment. These devices are not intended to be used to treating cancer of the prostate.

The HF-Resection Electrode for Plasma Vaporization is a bipolar instrument designed and intended for use in urological surgical procedures involving the vaporization, ablation, coagulation, cutting, removal of soft tissue and coagulation where hemostasis is required. The specific soft tissue indications include use in the prostate, bladder and bladder neck. The

specific treatment indications include benign prostate hyperplasia BPH, bladder cancer, tumors, lesions and neoplasms. The specific urological indications include transurethral electrovaporization (TUVP, TVP, TUEVP), also known as transurethral vapor resection of the prostate (TUVRP) or transurethral vaporization in saline (TUVis). These devices are intended to be used in an irrigated environment. These devices are not intended to be used in treating cancer of the prostate.

6. Comparison of Technological Characteristics:

The HF Resection Electrodes and the HF Resection Button Electrode for Plasma vaporization are identical to the predicate devices in intended use, design and material specification. The only difference is the new cable (WA00014A) that now allows for the electrodes and working elements to be connected to the ESG-400 (K103032).

The cable is equivalent to WA00013A that allows for the electrodes and working elements to be connected to the UES-40 (K030194 and K100275). The only difference is with the plug.

7. Summary of Non-Clinical Performance Testing:

Design verification was performed to ensure the device functions according to its intended use and the results met their acceptance criteria.

Bench Testing according to the FDA-recognized consensus standards IEC 60601-1 and IEC 60601-2-2 was conducted to demonstrate that the design change does not raise any new concerns regarding electrical safety.

Risk analysis was carried out in accordance with established in-house acceptance criteria based on ISO 14971:2007.

8. Summary of Clinical Tests Submitted or Referenced:

No clinical tests were performed or referenced in support of this Special 510(k).

9. Conclusion:

Olympus Winter & Ibe GmbH believes that the HF Electrosurgical Resection and Vaporization Electrode Series is substantially equivalent to the currently legally marketed devices. It does not introduce new indications for use, has the same technological characteristics and does not introduce new potential hazards or safety risks.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Olympus Winter & Ibe GmbH
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Ms. Sheri Musgnung
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JUN 2 0 2012

Re: K120418
Trade/Device Name: Electrosurgical Resection and Vaporization Electrode Series
HF-Resection Electrode for Plasma Vaporization, Model WA22557C
HF-Resection Electrode Series, Models WA22301D, WA22302D, WA22503D, WA22305D, WA22306D, WA22507D, WA22537D, WA22521C, WA22523C, WA22331D, WA22332D, WA22538C, WA22539D, WA22351C, WA22438C, WA22355C, WA22351A, WA22355A, WA22558C
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulatory Class: II
Product Code: FAS, GEI
Dated: May 18, 2012
Received: May 21, 2012

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.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: HF- Resection Electrode Series

Model Numbers:

WA22301D, WA22302D, WA22503D, WA22305D, WA22306D, WA22507D, WA22537D, WA22521C, WA22523C, WA22331D, WA22332D, WA22538C, WA22539D, WA22351C, WA22438C, WA22355C, WA22351A, WA22355A, WA22558C

Indications For Use:

The HF-Resection Electrodes are a bipolar instrument series designed and intended for use in endoscopic urological surgical procedures involving the resection, ablation or removal of soft tissue and where hemostatis is required. The specific urological indications include use in the prostate, bladder and bladder neck. The procedures for which the devices can be used for are transurethral resection in saline (TURis), transurethral prostatectomy, transurethral resection of the prostate (TURP) for benign prostatic hypertplasia, transurethral incision of the prostate (TUIP) or bladder neck, transurethral resection of bladder tumors (TURBT) and cystodiathermy. These devices are intended to be used in an irrigated environment.

These devices are not intended to be used for treating cancer of the prostate.

Prescription Use ✓ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120418

Indications for Use

510(k) Number (if known):_____

Device Name: HF- Resection Electrode for Plasma Vaporization

Model Number: WA22557C

Indications For Use:

The HF-Resection Electrode for Plasma Vaporization is a bipolar instrument designed and intended for use in urological surgical procedures involving the vaporization, ablation, coagulation, cutting, removal of soft tissue and coagulation where hemostasis is required. The specific soft tissue indications include use in the prostate, bladder and bladder neck. The specific treatment indications include benign prostate hyperplasia BPH, bladder cancer, tumors, lesions and neoplasms. The specific urological indications include transurethral electrovaporization (TUVP, TVP, TUEVP), also known as transurethral vapor resection of the prostate (TUVRP) or transurethral vaporization in saline (TUVis). These devices are intended to be used in an irrigated environment.

These devices are not intended to be used in treating cancer of the prostate.

Prescription Use__✓__ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120418