K100275

JUL - 1 2010

510(k) SUMMARY

Section 1 General Information

■ **Applicant**	Olympus Winter & Ibe GmbH Kuehnstrasse 61 * 22045 Hamburg * Germany Establishment Registration No: 9610773
■ **Official Correspondent**	Stacy Abbatiello Kluesner, M.S., RAC Regulatory Affairs & Quality Assurance Olympus America Inc. 3500 Corporate Parkway PO Box 610 Center Valley, PA 18034-0610 Phone: 484-896-5405 FAX: 484-896-7128 Email: Stacy.Kluesner@Olympus.com Establishment Registration No.: 2429304
■ **Manufacturer**	Olympus Winter and Ibe GmbH Kuehnstrasse 61 * 22045 Hamburg * Germany Establishment Registration No.: 9610773

Section 2 Device Identification

Device Name:	Electrosurgical Resection and Vaporization Electrode Series
Common Name:	Electrosurgical Cutting & Coagulation Device & Accessories Electrode, Electrosurgical, Active, Urological
Regulation Number:	21 CFR 878.4400 21 CFR 876.4300 21 CFR 876.1500
Regulation Name:	Electrosurgical cutting and coagulation device and accessories Endoscopic electrosurgical unit and accessories Resectoscope Resectoscope Working Element
Regulatory Class:	II
Product Code:	FAS, GEI, FJL, FDC
Classification Panel	General and Plastic Surgery Gastroenterology and urology

3 Predicate Device Information

Predicate Devices for HF Resection Electrodes

510(k)	Device Name	Manufacturer
K903233	Resectoscope Loops	Olympus
K994166	Gyrus Axipolar Resectoscope Electrode	Gyrus ACMI
K030194	Electrosurgical Unit and its associated accessories, HF Resection Electrode	Olympus

Predicate Devices for HF Resection Button Electrode for Plasma Vaporization

510(k)	Device Name	Manufacturer
K903233	Resectoscope Loops	Olympus
K973820	CIRCON ACMI USA Elite System VaporTrode Vaporization Electrode and VaporTome Resection Electrode	Gyrus ACMI
K994166	Gyrus Axipolar Resectoscope Electrode	Gyrus ACMI
K030185	Gyrus PlasmaKinetic Superpulse System	Gyrus Inc

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.

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 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 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 hemostatis 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 to treating cancer of the prostate.

6 Comparison of Technological Characteristics

The HF Resection Electrodes and the HF Resection Button Electrode for Plasma Vaporization are basically identical to the predicate devices in intended use, design and material specifications.

7 Conclusion

When compared to the predicate devices, HF Resection Electrodes and the HF Resection Button Electrode for Plasma Vaporization do not incorporate any significant changes that could affect the safety or effectiveness of the device.

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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Center Valley, PA 18034-0610

JUL -1 2010

Re: K100275
Trade/Device Name:
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: January 29, 2010
Received: February 1, 2010

Dear Ms. Abbatiello Kluesner:

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

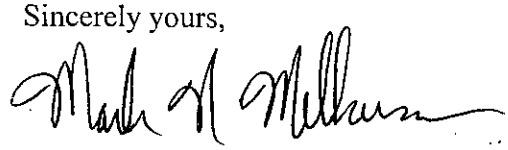
found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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 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,



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, WA222306D, 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 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 to 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 K100275

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 hemostatis 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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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