



Food and Drug Administration  
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July 11, 2016

Ace Medical Devices Pvt. Ltd.  
% Traves Brady  
Managing Member  
Pacific Surgical Specialties, LLC  
428 W 21st Ave  
Spokane, WA 99203

Re: K153055  
Trade/Device Name: ACE Electrosurgical Resection and Vaporization Electrodes Series  
Regulation Number: 21 CFR§ 878.4400  
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories  
Regulatory Class: II  
Product Code: GEI, FAS  
Dated: June 2, 2016  
Received: June 3, 2016

Dear Traves Brady:

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

## Indications for Use

510(k) Number (if known)

K153055

Device Name

ACE Electrosurgical Resection and Vaporization Electrodes Series

Indications for Use (Describe)

The ACE Electrosurgical Resection and Vaporization Electrodes Series is a single use bipolar electrode series designed and intended for use in endoscopic urological surgical procedures involving the resection, ablation or removal of soft tissue and coagulation 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 (TURP), 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 (0.9% Sodium Chloride). These devices are not intended to be used to treat cancer of the prostate.

The ACE Electrosurgical Resection and Vaporization Electrode Series are single use bipolar electrodes designed and intended for use in urological surgical procedures involving the vaporization, ablation, 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 electro vaporization (TUVV, 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 (0.9% Sodium Chloride). These devices are not intended to be used in treating cancer of the prostate.

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.

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## Section 5 – 510(k) Summary

### ACE Electrosurgical Resection and Vaporization Electrodes Series

**K153055**

**1. Submission Sponsor**

Ace Medical Devices Pvt. Ltd.

E-1/7, Neptune Society

Kalyani Nagar

Pune - 411006

Maharashtra, India

Phone number: +91-20-26681483

Contact: Mr. Vikas Sethi

Title: Managing Director

**2. Submission Correspondent**

Pacific Surgical Specialties, LLC

428 W 21<sup>st</sup> Ave

Spokane

WA, 99203

USA

855.447.3222

Contact: Traves Brady

Title: Managing Member

**3. Date Prepared**

July 7, 2016

#### 4. Device Identification

Trade/Proprietary Name: ACE Electrosurgical Resection and Vaporization Electrodes Series

Common/Usual Name: Endoscopic electrosurgical unit and accessories

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

Regulation Number: 21 CFR §878.4400  
21 CFR §878.4300

Product Code: GEI, Electrosurgical Cutting, and Coagulation Device & Accessories  
FAS, Endoscopic electrosurgical unit, and accessories

Device Class: Class II

Classification Panel: Gastroenterology and Urology

#### 5. Legally Marketed Predicate Device(s)

K120418, Electrosurgical Resection and Vaporization Electrodes Series, Olympus Winter & Ibe GmbH

#### 6. Device Description

The ACE Electrosurgical Resection and Vaporization Electrodes Series consist of an active tip, PTFE color code identification, and an insulator between the electrode tube, a guiding tube, telescope clip and arm (shaft). The design and dimensions of the electrode tips vary to accommodate various procedural conditions. The active tips of the various electrodes may consist of loops or buttons. The system includes single-use electrodes that can be connected to a working element (only WA22367A or WA22366A – K100275), or the use of the single-use electrodes together other compatible electrosurgical cables as applicable. Compatible Generators to any of the electrodes include generators with output specifications that meet the following criteria: 100-120/220-240V, ~50-60Hz/1000VA, 310-380 kHz, 320W/200  $\Omega$ , Int 10s/30s.

#### 7. Indication for Use Statement

The ACE Electrosurgical Resection and Vaporization Electrodes Series is a single use bipolar electrode series designed and intended for use in endoscopic urological surgical procedures involving the resection, ablation or removal of soft tissue and coagulation 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 (TURP), 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 (0.9% Sodium Chloride). These devices are not intended to be used to treat cancer of the prostate.

The ACE Electrosurgical Resection and Vaporization Electrode Series are single use bipolar electrodes designed and intended for use in urological surgical procedures involving the vaporization, ablation, 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 electro vaporization (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 (0.9% Sodium Chloride). These devices are not intended to be used in treating cancer of the prostate.

**8. Substantial Equivalence Discussion**

The following table compares the ACE Electrosurgical Resection and Vaporization Electrodes Series to the predicate device with respect to indications for use, principles of operation, technological characteristics, materials, and performance testing. The comparison of the devices provides more detailed information regarding the basis for the determination of substantial equivalence. The subject device does not raise any new issues of safety or effectiveness based on the similarities to the predicate device.

**Table 5A – Comparison of Characteristics**

<b>Manufacturer</b>	<b>Ace Medical Devices Pvt. Ltd.</b>	<b>Olympus Winter &amp; Ibe GmbH</b>
<b>Trade Name</b>	<b>ACE Electrosurgical Resection and Vaporization Electrodes Series</b>	<b>Electrosurgical Resection and Vaporization Electrodes Series</b>
<b>510(k) Number</b>	K153055	K120418
<b>Product Code</b>	FAS, GEI	FAS, GEI, FJL, FDC
<b>Regulation Number</b>	21 CFR §876.4400, 21 CFR §876.4300	21 CFR §876.4400, 21 CFR §876.4300, 21 CFR §876.1500
<b>Regulation Name</b>	Endoscopic electrosurgical unit and accessories	Endoscopic electrosurgical unit and accessories
<b>Indications for Use</b>	The ACE Electrosurgical Resection and Vaporization Electrodes Series is a single use bipolar electrode series designed and intended for use in endoscopic urological surgical procedures involving the resection, ablation or removal of soft tissue and coagulation 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	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),

Manufacturer	Ace Medical Devices Pvt. Ltd.	Olympus Winter & Ibe GmbH
Trade Name	ACE Electrosurgical Resection and Vaporization Electrodes Series	Electrosurgical Resection and Vaporization Electrodes Series
	<p>used are transurethral resection in saline (TURis), transurethral prostatectomy (TURP), 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 (0.9% Sodium Chloride). These devices are not intended to be used to treat cancer of the prostate.</p> <p>The ACE Electrosurgical Resection and Vaporization Electrode Series are single use bipolar electrodes designed and intended for use in urological surgical procedures involving the vaporization, ablation, 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 electro vaporization (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 (0.9% Sodium Chloride). These devices are not intended to be used in treating cancer of the prostate.</p>	<p>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.</p> <p>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.</p>
<b>Principles of Operation</b>	Uses energy for cutting and removal of tissue during urologic procedures	Uses energy for cutting and removal of tissue during urologic procedures
<b>Energy Type</b>	Use bipolar energy to perform electrocautery	Use bipolar energy to perform electrocautery
<b>Materials</b>	Tungsten, Tungsten alloy, Aluminum Oxide, Stainless Steel 304, Polytetrafluoroethylene (PTFE)	Tungsten, Tungsten alloy, Aluminum Oxide, Stainless Steel 304, Polytetrafluoroethylene (PTFE)
<b>Biocompatibility</b>	Cytotoxicity, Sensitization, Intracutaneous Reactivity, Acute Systemic Toxicity,	Cytotoxicity, Sensitization, Irritation or Intracutaneous Reactivity

<b>Manufacturer</b>	<b>Ace Medical Devices Pvt. Ltd.</b>	<b>Olympus Winter &amp; Ibe GmbH</b>																																													
<b>Trade Name</b>	<b>ACE Electrosurgical Resection and Vaporization Electrodes Series</b>	<b>Electrosurgical Resection and Vaporization Electrodes Series</b>																																													
	Implantation																																														
<b>Sterile</b>	Electrodes are Sterile packed. Ethylene Oxide (EO) SAL 10 <sup>-6</sup>	Electrodes are Sterile packed. Ethylene Oxide (EO) SAL 10 <sup>-6</sup>																																													
<b>Overall Design</b>	The ACE Electrosurgical Resection and Vaporization Electrodes Series consist of an active tip, PTFE color code identification, and insulator between the electrode tube, a guiding tube, telescope clip and arm (shaft).	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).																																													
<b>System</b>	The system includes Electrodes that can be connected to an electrical surgical unit.	The system includes Electrodes, working elements, and an HF bipolar cable that can be connected to an electrical surgical unit.																																													
<b>Electrode Tips</b>	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, needles or buttons	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																																													
<b>PTFE Color Code</b>	<p>Yellow, Gray, Blue, Red, White</p> <table border="1"> <thead> <tr> <th>Color</th> <th>Inner sheath [Fr.]</th> <th>Outer Sheath</th> </tr> </thead> <tbody> <tr> <td>Yellow</td> <td>24</td> <td>26/27</td> </tr> <tr> <td>White</td> <td>24/26/28</td> <td>26/27/28.5</td> </tr> <tr> <td>Gray</td> <td>24/26/28</td> <td>26/27/28.5</td> </tr> <tr> <th colspan="3">Direction of view</th> </tr> <tr> <td>Red</td> <td></td> <td>30°</td> </tr> <tr> <td>Blue</td> <td></td> <td>12°</td> </tr> <tr> <td>White</td> <td></td> <td>12°/30°/45°</td> </tr> </tbody> </table>	Color	Inner sheath [Fr.]	Outer Sheath	Yellow	24	26/27	White	24/26/28	26/27/28.5	Gray	24/26/28	26/27/28.5	Direction of view			Red		30°	Blue		12°	White		12°/30°/45°	<p>Yellow, Gray, Blue, Red, White</p> <table border="1"> <thead> <tr> <th>Color</th> <th>Inner sheath [Fr.]</th> <th>Outer Sheath</th> </tr> </thead> <tbody> <tr> <td>Yellow</td> <td>24</td> <td>26/27</td> </tr> <tr> <td>Gray</td> <td>24/26/28</td> <td>27/28.5</td> </tr> <tr> <td>Blue</td> <td colspan="2">For resection with saline solution</td> </tr> <tr> <th colspan="3">Direction of view</th> </tr> <tr> <td>Red</td> <td></td> <td>30°</td> </tr> <tr> <td>White</td> <td></td> <td>12°/30°</td> </tr> </tbody> </table>	Color	Inner sheath [Fr.]	Outer Sheath	Yellow	24	26/27	Gray	24/26/28	27/28.5	Blue	For resection with saline solution		Direction of view			Red		30°	White		12°/30°
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<b>Single-Use</b>	Electrodes are intended for single use only	Electrodes are intended for single use only HF bipolar Cable is reusable																																													
<b>Packaging</b>	Simple Tyvek pouch with retaining card and protective sheath over sharp end	Simple Tyvek pouch with retaining card and protective sheath over sharp end																																													
<b>Shelf Life</b>	3 years	3 years																																													
<b>Electrical Safety</b>	Conforms to IEC 60601	Conforms to IEC 60601																																													
<b>Thermal Safety</b>	Conforms to IEC 60601-2-2	Conforms to IEC 60601-2-2																																													

## 9. Comparison of Technological Characteristics

The ACE Electrosurgical Resection and Vaporization Electrodes Series are identical to the predicate devices in intended use, design and material specification.

When the electrodes are used with the UES-40 (K030194 and K100275), and the ESG-400 (K103032) the standard reusable Olympus cables are used.

## 10. Non-Clinical Performance Data

Design verification was performed to ensure the device functions according to its intended use, and the results met their acceptance criteria. Risk analysis was carried out in accordance with established in-house acceptance criteria based on ISO 14971:2007.

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.

## 11. Clinical Performance Data

There was no human clinical testing required to support the medical device as the indications for use is equivalent to the predicate device. These types of devices, including the predicate devices, have been on the market for many years with proven safety and efficacy for the use of the device. The non-clinical testing detailed in this submission supports the substantial equivalence of the device.

## 12. Statement of Substantial Equivalence

The ACE Electrosurgical Resection and Vaporization Electrodes Series, as designed and manufactured, is determined to be 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.