DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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April 5, 2017

Richard Wolf Medical Instruments Corporation
Mr. Michael Loiterman
US Head of Regulatory - QA/QC
353 Corporate Woods Parkway
Vernon Hills, Illinois 60061

Re: K170377
Trade/Device Name: TipControl RF Instrument bipo Ø 2.5mm WL 280mm, TipControl RF Instrument bipo Ø 2.5mm WL 350mm
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: February 3, 2017
Received: February 7, 2017

Dear Mr. Loiterman:

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,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical 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)*
K170377

Device Name
TipControl RF Instrument bipo Ø 2.5mm Wl 280mm, TipControl RF Instrument bipo Ø 2.5mm Wl 350mm

Indications for Use *(Describe)*
The RF instruments are used for tissue and vessel coagulation (hemostasis) by means of radio-frequency current.
The products are intended for use in endoscopically performed or supported surgeries. The types of surgery intended are:

* Endoscopic procedures
* Orthopedic coagulation
* Neurosurgical coagulation

The products are exclusively intended for use by specialized medical personnel and may only be used by adequately qualified and trained medical personnel.

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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5. 510(k) Summary

Submitter:			Date of Preparation: February 3, 2017 Revised 04-04-2017
Company / Institution name: **RICHARD WOLF MEDICAL INSTRUMENTS CORP.**			FDA establishment registration number: 14 184 79
Division name (if applicable): N.A.			Phone number (include area code): (847) 913 1113
Street address: 353 Corporate Woods Parkway			FAX number (include area code): (847) 913 0924
City: Vernon Hills	State/Province: Illinois	Country: USA	ZIP / Postal Code: 60061
Contact name: Mr. Michael G. Loiterman			
Contact title: US Head of Regulatory – QA/QC			
Parent Company:			
Company / Institution name: **Richard Wolf GmbH**			FDA establishment registration number: 96 111 02
Street address: Pforzheimer Str. 32			
City: Knittlingen	State/Province: Baden-Württemberg	Country: Germany	ZIP / Postal Code: 75438
Product Information:			
Trade names: RF INSTRUMENT BIPO Ø 2.5MM WL 280MM RF INSTRUMENT BIPO Ø 2.5MM WL 350MM		Model numbers: 49936911 49936921	
Common name: TipControl RF Instrument, bipo		Classification name: GEI, 878.4400 Electrosurgical cutting and coagulation device and accessories.	
Information on devices to which substantial equivalence is claimed:			
510(k) No.: K003126	Trade or proprietary or model name: Trigger Flex™ Bipolar Electrode		Manufacturer: ELLMAN INTL., INC.

5.1 Description

The TipControl RF (Radio Frequency) Instruments, bipo are disposable single-use, sterile packaged electrosurgical devices, used for tissue and vessel coagulation (hemostasis) by means of radio-frequency current. The products are intended for use in endoscopic performed or supported surgeries. The types of surgery intended are: Endoscopic procedures, orthopedic coagulation, and neurosurgical coagulation. These products are exclusively intended for use by specialized medical personnel and may only be used by adequately qualified and trained medical personnel.

The TipControl RF Instrument, bipo consists of a handle, a sheath tube, the TipControl RF electrode and a connection cable with an US 2-PIN device connector. The just mentioned components comprise a complete unit for disposable use and cannot be dismantled. They are currently available in a working length of 280 mm or 350 mm.

The TipControl RF Instruments, bipo are designed to be used in conjunction with the electrosurgical bipolar radiofrequency generators Surgitron and Surgi-Max Plus up to 4 MHz and endoscopic accessories. The RF generator provides power and delivers electrical current to the distal tips of the RF instruments.

The TipControl RF Instruments, bipo are manufactured in accordance with standards for quality management (ISO 13485, ISO 9001), for electrical medical devices (IEC 60601), for sterilization (ISO 11135), and for biological safety (ISO 10993).

5.2 Indications for Use

The RF instruments are used for tissue and vessel coagulation (hemostasis) by means of radio-frequency current.

The products are intended for use in endoscopically performed or supported surgeries. The types of surgery intended are:

* Endoscopic procedures
* Orthopedic coagulation
* Neurosurgical coagulation

The products are exclusively intended for use by specialized medical personnel and may only be used by adequately qualified and trained medical personnel.

5.3 Substantial Equivalence

The following information summarizes the technological characteristics' comparison of the submitted TipControl RF Instruments, bipo versus the predicate device Trigger-Flex™ Bipolar Electrode (K003126).

5.3.1 Similarities

The submitted instruments and the predicate devices share equivalent indications for use. They have an equivalent basic operational design and use equivalent materials. Both are used in conjunction with bipolar electrosurgical radiofrequency generators, sharing equivalent technical specifications. Both the instruments and the predicate are single-use and sterile provided. And both comply with the relevant safety standards of IEC 60601.

5.3.2 Main Differences

Working Lengths

The shortest working length of the submitted instrument is 280mm vs. 240mm of the predicate instruments. The longest working length of the submitted instruments is 350mm vs. 320mm for the predicate instruments.

Diameter of the Electrode Tip

The diameter of the electrode tip (2.5mm) is 0.5mm thinner than in the predicate instrument (3.0mm).

Sterilization Method

The submitted instruments are sterilized via ethylene oxide (EO) sterilization, predicate instruments former via gamma radiation and actual with EO.

Product Packaging

While predicate instruments are packaged into sealed Tyvek pouches, the herein submitted instruments additionally utilize a PETG blister.

5.4 Performance Data

5.4.1 Sterilization

The TipControl RF Instruments, bipo comply with the applicable requirements of the FDA-recognized standards listed below:

- Recognition Number 14-452: ISO 11135 Second edition 2014, sterilization of health-care products - ethylene oxide - requirements for the development, validation and routine control of a sterilization process for medical devices. (Sterility)
- Recognition Number 14-408: ISO 10993-7 Second edition 2008-10-15, biological evaluation of medical devices - part 7: ethylene oxide sterilization residuals [including: technical corrigendum 1 (2009)]. (Sterility)

5.4.2 Bench Testing

The TipControl RF Instruments, bipo perform successfully in bench testing, conducted in alignment with the following FDA guidances:

- "Evaluation of Medical Devices - Part 1: Evaluation and testing within a risk management process" issued June 16, 2016
- "Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery" issued August 15, 2016
- "Premarket Notification (510(k)) Submissions for Bipolar Electrosurgical Vessel Sealers for General Surgery" issued August 15, 2016

5.4.3 Biocompatibility Testing

Biocompatibility Test Results:

Test	Conclusion
ISO 10993-5: Cytotoxicity Study (XTT Assay)	non-cytotoxic
ISO 10993-4, -12: Hemolysis Study (Extract Only)	non-hemolytic
ISO 10993-10, -12: Intracutaneous Reactivity Study in Rabbit	non-irritating
ISO 10993-10, -12 and OECD Guideline 429 and Commission Regulation EC No. 440/2008, B.42: Skin Sensitization Study in Mice (LLNA)	non-sensitizing
ISO 10993-11, -12: Systemic Toxicity Study in Mice	non-toxic

5.4.4 Electrical Safety and Electromagnetic Compatibility

The TipControl RF Instruments, bipo fully comply with the applicable requirements of the FDA-recognized standards listed below:

- Recognition No. 19-4, IEC 60601-1:2005/(R)2012 and A1:2012,, c1:2009/(r)2012 and a2:2010/(r)2012 (consolidated text) medical electrical equipment - part 1: general requirements for basic safety and essential performance (IEC 60601-1:2005, mod). (ES/EMC)
- Recognition No. 6-336, IEC 60601-2-2 Edition 5.0 2009-02, 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 [including: technical corrigendum 1 (2014)]. (General Plastic Surgery/General Hospital**)**
- Recognition No. 9-91, IEC 60601-2-18: Edition 3.0 2009-08, medical electrical equipment - part 2-18: particular requirements for the basic safety and essential performance of endoscopic equipment. (ObGyn/Gastroenterology/Urology)

5.4.5 Software Verification and Validation Testing

The products do not contain software.

5.4.6 Animal Studies and Clinical Studies

Neither animal studies nor clinical studies were conducted in order to demonstrate substantial equivalence.

5.5 Conclusions

The submitted TipControl RF Instruments, bipo and the Trigger-Flex™ Bipolar Electrode (K003126) share equivalent indications for use.

The technological differences do not raise new types of questions with regard to safety and efficacy. Validation testing has shown that the TipControl RF Instruments, bipo perform in accordance with their technological specifications and operate as intended. Devices are as safe and effective as predicate devices.

Thus, substantial equivalency to the aforementioned 510(k)-cleared predicate devices has been demonstrated.