DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 23, 2017

Chirurgie Innovation
% Mark Job
Official Correspondent
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, MN 55313

Re: K163090
Trade/Device Name: Plasma EDGE System
Regulation Number: 21 CFR§ 876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulatory Class: II
Product Code: FAS, GEI, FDC
Dated: May 15, 2017
Received: May 16, 2017

Dear Mark Job:

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,

Charles Viviano -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)*

K163090

Device Name
Plasma EDGE System

Indications for Use *(Describe)*

The Plasma Edge System single use bipolar resection electrodes are used for the ablation and hemostasis of tissues under endoscopic control, in association with endoscopic accessories. They are intended for endoscopic surgeries with saline irrigation, in the field of urology. The use of the Plasma Edge System is restricted to surgeons, specialized in urological surgery, for specific use in:

- Transurethral resection of prostate (TURP) for benign prostatic hyperplasia
- Transurethral incision of the prostate (TUIP) or bladder neck
- Transurethral resection of bladder tumors (TURBT)
- Cystodiathermy
- Transurethral Vaporization of the prostate (TUVP/TVP) for benign prostatic hyperplasia, and for Transurethral Vaporization of bladder tumors. (MVVS and MVV models only)

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			
Applicant		Chirurgie Innovation	
Device :	Plasma Edge System	Traditional 510(k) application	
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SECTION 5:
510(K) SUMMARY

Submitter	Chirurgie Innovation 27 Place Victor Schoelcher F-91300 Massy FRANCE
Contacts	Guillaume Noury CEO regulatory@orange.fr Phone : +33 6 16 16 63 30
Date	07/29/2016
Trade Name	Plasma EDGE System
Common name	Bipolar electrodes
Classification Name	Electrosurgical cutting and coagulation device and accessories Resectoscope, working element
Class	II
Product Code	**Classification product code** : FAS **Subsequent product code** : GEI / FDC
CFR section	876.4300 / 878.4400 / 876.1500
Device panel	**Regulation Medical Specialty** : Gastroenterology / Urology **510k Review Panel** : General & Plastic Surgery
Legally marketed predicate devices	**K994166**: Axipolar Resectoscope Electrode – manufactured by Gyrus Medical Ltd. **K120567**: Gyrus ACMI PK® Button Electrode – manufactured by Gyrus Medical Ltd.

Product Description

The Plasma Edge system is a manual surgical device, consisting of a single-use electrode with cable range, an active and passive working element reusable and an adaptator to an HF generator compatible.

The electrodes consist of an active tip, two wires threaded through ceramic tubes to connect the active tip to the body of the loop, allowing the HF energy to reach the active tip.

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It has to be used with continuous flow irrigation of saline solution (NaCl 0,9%) that reaches the operative site through a resectoscope. The HF energy delivered from the generator to the electrode ionizes the gas of the saline solution, creating a plasma for the cutting, coagulation and vaporization of tissues.

Electrodes range:

The list of electrodes is divided in 2 ranges: SIDE LOAD and FRONT LOAD.
Each range got is specific way to be assembly into the working element. The only physical difference between both ranges is the electrode cable connexion.
End user can be used to both versions so we decided to offer the choice between them.

Working element range:

The working elements are compatible with the 3 main existing optics brands: STORZ, ACMI and OLYMPUS.
The working elements will be divided in 2 families: side load connection and front load connection.

Adaptor:

This will allow to connect the Plasma EDGE electrode range to a bipolar HF generator system

Indications for use

The Plasma Edge System single use bipolar resection electrodes are used for the ablation and hemostasis of tissues under endoscopic control, in association with endoscopic accessories. They are intended for endoscopic surgeries with saline irrigation, in the field of urology. The use of the Plasma Edge System is restricted to surgeons, specialized in urological surgery, for specific use in:

- Transurethral resection of prostate (TURP) for benign prostatic hyperplasia
- Transurethral incision of the prostate (TUIP) or bladder neck
- Transurethral resection of bladder tumors (TURBT)

- Cystodiathermy
- Transurethral Vaporization of the prostate (TUVP/TVP) for benign prostatic hyperplasia, and for Transurethral Vaporization of bladder tumors. (MVVS and MVV models only)

Performance testing

Risk analysis:

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

Performance tests were carried out to ensure that the system functions as intended and meets design specifications. The following performance tests and usability studies were conducted:

Biocompatibility testing

The biocompatibility evaluation for the subject device was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995. The testing included the following tests: ▪ Biological Safety – toxicology: AAMI ANSI ISO 10993-1:2009; Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process ▪ Cytotoxicity: AAMI ANSI ISO 10993-5:2009; Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity ▪ Chemical Analysis: AAMI ANSI ISO 10993-12:2012; Biological evaluation of medical devices - Part 12: Sample Preparation and Reference Materials

Electrical safety

Electrical Safety was tested by an independent laboratory according to AAMI/ANSI ES 60601-1:2005 and C1:2009 and A2:2010; Medical Electrical Equipment - Part 1.1 General requirements for safety and essential performance.

Electromagnetic compatibility (EMC)

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Electromagnetic compatibility with the existing HF generator was tested by an independent laboratory according to IEC 60601-1 -2 : 2007

Cleaning and sterilization validation for the reusable working element range:

Steam sterilization validation was tested by an independent laboratory following AAMI TIR N°12, ISO 17664 and ISO 17665

Cleaning and disinfection validation was tested by an independent laboratory following AAMI TIR N°30

Bench top validation testing

End of life simulation report, breakdown simulation report, working element compatibility report and test on ex vivo tissues have been tested on the Plasma Edge System to demonstrate the product safety and the efficiency.

Summary of Sterilization and Shelf Life Discussion

The electrodes are delivered in a sterile state and are intended for single patient use only. The validated sterilization method used is ethylene oxide. The product has a shelf life of three (3) years.

List of standards

Standards	Description
ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
ISO 10993-5	Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity
ISO 10993-7	Biological evaluation of medical devices - part 7: ethylene oxide sterilization residuals [including: technical corrigendum 1 (2009)]
ISO 10993-10	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

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Standards	Description
ISO 10993-11	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
ISO 11135	Sterilization of health-care products - ethylene oxide - requirements for the development, validation and routine control of a sterilization process for medical devices
ISO 11607-1	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
ISO 11607-2	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
ISO 17664 ISO 17665-1 AAMI TIR N°12	Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices Sterilization of health care products -- Moist heat -- Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
AAMI TIR N°30	Cleaning and disinfection validation: following FDA guidance "Reprocessing medical device in health care settings: validation methods and labeling guidance for industry and food administration staff issued March 17, 2015"
IEC 60601-1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2	General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests
IEC 60601-1-6	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 60601-2-2	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

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Standards	Description
IEC 60601-2-18	Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment
IEC 62366	Medical devices – Application of usability engineering to medical devices
ISO 14971	Medical devices - application of risk management to medical devices.
ISO 15223-1	Medical devices – symbols to be used with medical device labels, labeling, and information to be supplied – part 1 : general requirements

Comparison of Technological characteristics:

ELECTRODE	**Proposed device** Plasma Edge (cutting loop electrode / vaporization electrode)	**Predicate device** Axipolar Resectoscope Electrode (K994166)	**Predicate device** Gyrus ACMI PK® Button Electrode (K120567)
Indications for use	- Transurethral resection of prostate (TURP) - Transurethral incision of the prostate (TUIP) or bladder neck - Transurethral resection of bladder tumours (TURBT) - Cystodiathermy -Transurethral electrovaporization of the prostate	- Transurethral resection of prostate (TURP) - Transurethral incision of the prostate (TUIP) or bladder neck - Transurethral resection of bladder tumours (TURBT) - Cystodiathermy -	- Transurethral electrovaporization of the prostate
Sterilization	Eto	Eto	

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ELECTRODE	Proposed device Plasma Edge (cutting loop electrode / vaporization electrode)	Predicate device Axipolar Resectoscope Electrode (K994166)	Predicate device Gyrus ACMI PK® Button Electrode (K120567)
Disposable	Yes	Yes	
Energy type	High frequency	High frequency	
Mode	Bipolar	Bipolar	
User interface	Footswitch	Footswitch	
Use only in Conductive Media	The electrode is to be activated only when immersed in a conductive media such as standard saline solution	The electrode is to be activated only when immersed in a conductive media such as standard saline solution	
Electrode manipulation	Working element	Working element	
Working element compatibility	Storz Olympus ACMI	Storz Olympus ACMI	
Sterilization of working element	Autoclave	Autoclave	

Conclusion:

There is no difference between the Plasma EDGE resection system and the predicate devices in terms of intended use, principle of operation, and the technology used for device performance. In other words, there is no difference technically, clinically and biologically.

The Plasma EDGE resection system was subjected to verification testing to confirm device performance. There is no new technology and no difference that would raise new or different questions of safety or efficiency. Comparative performance testing demonstrate that the device performed as well as, or better than, the predicate device.