



June 12, 2024

Lamidey Noury Medical
Guillaume Noury
CEO
Z.A Les godets, 3 rue des petits ruisseaux
Verrières le buisson, 91370
FRANCE

Re: K240504
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: February 19, 2024
Received: February 21, 2024

Dear Guillaume Noury:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See

the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark R. Kreitz -S

for Mark J. Antonino, M.S.

Assistant Director

DHT3B: Division of Reproductive,

Gynecology and Urology Devices

OHT3: Office of Gastrorenal, ObGyn,

General Hospital, and Urology Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

Indications for Use

Submission Number (if known)

K240504

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 hypertrophy
- 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 hypertrophy, and for Transurethral Vaporization of bladder tumors. (MVVS 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Submitter	Lamidey Noury Medical Z.A. Les Godets, 3 rue des Petits Ruisseaux F-91370 Verrières le Buisson FRANCE
Contacts	Guillaume Noury CEO regulatory@orange.fr Phone : +33 169 20 30 21 Fax : +33 160 13 97 47
Date prepared	12/07/2023
Trade Name	Plasma EDGE System
Common name	Bipolar electrodes
Classification Name	Endoscopic Electrosurgical Unit and Accessories
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	K213135 : Plasme EDGE System – manufactured by LAMIDEY NOURY MEDICAL

i. Product Description

The Plasma Edge system is a manual surgical device, consisting of a single-use electrode, an active and passive working element reusable and an adaptor or only socket with memory (fixed cable) to connect them 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.

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.

a. Electrodes range:

The SIDE LOAD electrode range is composed by 4 electrodes with 4 active tips: thin, thick, knife (or needle) and vaporization. The SIDE LOAD electrodes are dedicated to being used with working element compatible with STORZ and OLYMPUS resectoscopes.

b. Working element range:

The SIDE LOAD working elements are compatible with STORZ and OLYMPUS resectoscope.

Electrodes are mechanically connected into a working element, used to move the electrode by a linear translation.

- With an active working element, action is pulling the electrode
- With a passive working element, action is pushing the electrode

c. Adaptor:

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

ii. 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 models only)

iii. Performance testing

a. Risk analysis:

Risk analysis was carried out in accordance with established in-house acceptance criteria based on ISO-14971:2019.

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.

b. Biocompatibility testing

The biocompatibility evaluation for the subject device was conducted in accordance with the standard ISO 10993-1:2018. To assess the impact on devices following DDM 0723-04 (change of cleaning solution and cleaning process) these tests have been performed:

- Rapport d'évaluation biologique_Résection (Biological evaluation report_Resection)
- Acute systemic toxicity test according to ISO 10993-11:2018. See report named "Report Acute Systemic Toxicity test -ISO 10993-11_Resection electrode_09-2023".
- Pyrogen detection assay according to European Pharmacopeia chapter 2.6.8 and ISO 10993-11:2018. See report named "Report Pyrogen detection-ISO 10993-11_Resection electrode_09-2023".
- Acute skin irritation test according to ISO 10993-23:2021. See report "Report Acute skin irritation-ISO 10993-23_Resection electrode_09-2023".
- Skin sensitization test on Guinea pig according to ISO 10993-10:2021. See report

"Report Skin sensitization test-ISO-10993-10_Resection electrode_09-2023".

- ISO MTS cytotoxicity test - ISO 10993-5 (2009): "Nettoyage X3_Cytotoxicité_QP2" & "Nettoyage X3_Cytotoxicité_QP3",

The previous biocompatibility test are available on previous versions of these documents.

c. Electrical safety

Electrical Safety was tested by an independent laboratory according to IEC 60601-1: 2012; Medical Electrical Equipment - Part 1.1 General requirements for safety and essential performance, and IEC 60601-2-2:2009- Medical Electrical Equipment - Part 2 Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories.

d. Electromagnetic compatibility (EMC)

Electromagnetic compatibility was tested by an independent laboratory according to the standard IEC 60601-1-2:2007. Electrode Plasma Edge was tested on the HF generator Gyrus and a comparison was realized with the assembly Electrode Gyrus on the HF generator Gyrus.

e. Cleaning and sterilization validation for the reusable working element range:

Cleaning and disinfection validation was tested by an independent laboratory following standards ISO 17664 and AAMI TIR N°30: manual cleaning.

Steam sterilization validation was tested by an independent laboratory following standards AAMI TIR N°12, ISO 17664 and ISO 17665: 132°C for 4 min.

f. Sterilization validation and Shelf-Life Discussion for single use electrode

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 four (4) years.

g. 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 on Gyrus Superpulse electrosurgical unit and MCB electrosurgical unit.

iv. 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
ISO 10993-11	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
ISO 10993-23	Biological evaluation of medical devices - Part 23: Tests for irritation
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	Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices
ISO 17665-1	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°12	Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers

AAMI TIR N°30	A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices
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
IEC 60601-2-18	Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment
IEC 62366-1	Medical Electrical Equipment - Part 1: 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
ISO 11737-1	Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products



v. Comparison of Technological characteristics:

	Proposed device Plasma EDGE System (Waiting for 510K number)	Predicate device Plasma EDGE System (K213135)	Substantial Equivalence Analysis
ELECTRODE			
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	SAME
Sterilization	Eto	Eto	SAME
Single use	Yes	Yes	SAME
Energy type	High frequency	High frequency	SAME
Mode	Bipolar	Bipolar	SAME
User interface	Footswitch	Footswitch	SAME
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	SAME
Electrode manipulation	Working element	Working element	SAME



	Proposed device Plasma EDGE System (Waiting for 510K number)	Predicate device Plasma EDGE System (K213135)	Substantial Equivalence Analysis
Working element compatibility	Storz Olympus	Storz Olympus	SAME
Sterilization of working element	Steam sterilization (autoclave)	Steam sterilization (autoclave)	SAME
MATERIALS OF ELECTRODES			
Active tip of thin and thick loop - WIRE	Tungsten wire 99,95%	Tungsten wire 99,95%	SAME
Active wire - WIRE	Platinum iridium	Platinum iridium	SAME
Insulation	Ceramic ZTA10	Ceramic ZTA10	SAME
Wire insulation	PTFE AWG28	PTFE AWG28	SAME
Heat-shrink tubing	MT 3000	MT 3000	SAME
Skeleton	Stainless Steel 316L	Stainless Steel 316L	SAME
Telescope clip	Polypropylene (DDM 0721-02)	Polypropylene (DDM 0721-02)	SAME



	Proposed device Plasma EDGE System (Waiting for 510K number)	Predicate device Plasma EDGE System (K213135)	Substantial Equivalence Analysis
Glue	Loctite M-121HP	Loctite M-121HP	SAME
Sealing gasket	Silicone	Silicone	SAME
Inner insulator	PEEK 450G	PEEK 450G	SAME
Connector over-moulding (SIDE load)	Polypropylene ISPLEN PP 080	Polypropylene ISPLEN PP 080	SAME
HF Cables of the electrodes	Silicone	Silicone	SAME
Plug	Tin-plated copper	Tin-plated copper	SAME
Crimp tube	Titanium	Titanium	SAME
Packaging material of Electrode			
Pouch material	- One side coated TYVEK® 1073B® Co 7502887C -One side PET/PE 60 Pharma (transparent)	- One side coated TYVEK® 1073B® Co 7502887C - -One side PET/PE 60 Pharma (transparent)	SAME
Blister material	PETG	PETG	SAME



At a high level, the subject and predicate devices are based on the same technological principle with the same elements:

- The indications for use (TURP; TUIP or bladder neck; TURBT; Cystodiathermy; Transurethral electrovaporization)
- The method of use (compatibility working element, conductive media, etc...)
- The material characteristics
- The modification of the cleaning solution and cleaning process parameters did not change the technological characteristics, the design nor fundamental operating principles of modified device compared to the predicate. The modification of the cleaning process were validated and did not lead to the identification of any new risk.

Since the indications for use and the technological characteristics are the same between the predicate device and the modified device subject of this Special 510(k), the modified device is substantially equivalent to the predicate device.

vi. 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 based upon the changes reported in this Special 510(k). In other words, there is no difference technically, clinically and biologically from the predicate.

The Plasma EDGE resection system was subjected to verification testing to confirm device performance. There is no new technology and differences 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.