March 2, 2022

Chirurgie Innovation
Guillaume Noury
CEO
Z.A. Les Godets, 3 Rue Des Petits Ruisseaux
Verrière le Buisson, 91370
France

Re: K213135
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: January 27, 2022
Received: January 31, 2022

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 (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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K213135

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 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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# 510(k) Summary

| | |
|---|---|
| Submitter | Chirurgie Innovation<br>Z.A. Les Godets, 3 rue des Petits Ruisseaux<br>F-91370 Verrières le Buisson FRANCE |
| Contacts | Guillaume Noury<br>CEO<br>regulatory@orange.fr<br>Phone : +33 169 20 30 21<br>Fax : +33 160 13 97 47 |
| Date | 01/27/2022 |
| Trade Name | Plasma EDGE system |
| Common name | Bipolar electrodes |
| Classification Name | Endoscopic Electrosurgical Unit and Accessories |
| Class | II |
| Product Code | **Classification product code** : FAS<br>**Subsequent product code** : GEI / FDC |
| CFR section | 876.4300 / 878.4400 / 876.1500 |
| Device panel | **Regulation Medical Specialty** : Gastroenterology / Urology<br>**510k Review Panel** : General & Plastic Surgery |
| Legally marketed predicate devices | **K163090**: Plasme EDGE System – manufactured by Chirurgie Innovation. |

## i. 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 adaptor to an HFgenerator 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 reachesthe operative site through a resectoscope. The HF energy delivered from the generator tothe electrode ionizes the gas of the saline solution, creating a plasma for the cutting, coagulation and vaporization of tissues.

## a. Electrodes range:

The list of electrodes is divided in 2 ranges: SIDE LOAD and FRONT LOAD.
The SIDE LOAD range is composed by 3 electrodes with 3 actives tips: thin, thick or vaporization. The SIDE LOAD electrodes are dedicated to being used with working element compatible with STORZ and OLYMPUS resectoscope.

The FRONT LOAD range is composed by 3 electrodes with 3 actives tips: thin, thick or vaporization. The FRONT LOAD electrodes are dedicated to being used with working element compatible with OLYMPUS resectoscope.

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.

## b. Working element range:

The working elements will be divided in 2 families: side load connection and front load connection. According to the working element families, the compatibility with resectoscope brands differs:

- SIDE LOAD connection: compatible with STORZ and OLYMPUS resectoscope.
- FRONT LOAD connection: compatible with 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; MVV models only)

## iii. Performance testing

### a. Risk analysis:

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

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.

### b. Biocompatibility testing

The biocompatibility evaluation for the subject device was conducted in accordance with the standard ISO 10993-1:2018. The testing included the following tests:

- Rapport d'évaluation biologique_Résection (Biological evaluation report_Resection)
- ISO MTS cytotoxicity test - ISO 10993-5 (2009): "Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity",
- ISO Acute Systemic Toxicity Study in Mice – Two Extracts - ISO 10993-11(2006): "Biological Evaluation of Medical Devices, Part 11: tests for systemic toxicity".
- ISO intracutaneous Study in Rabbits – Two Extracts - ISO 10993-10 (2010): "Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization"

- ISO Guinea Pig Maximization Sensitization Test – Two Extracts - ISO 10993-10 (2010): "Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization"

### 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 one (1) year.

### 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.

## 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 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<br>– 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 |
| 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**<br>Plasma EDGE System (K213135) | **Predicate device**<br>Plasma EDGE System (K163090) | **Substantial Equivalence Analyis** |
|---|---|---|---|
| **ELECTRODE** | | | |
| **Indications for use** | - Transurethral resection of prostate (TURP)<br>- Transurethral incision of the prostate (TUIP) or bladder neck<br>- Transurethral resection of bladder tumours (TURBT)<br>- Cystodiathermy<br>-Transurethral electrovaporization of the prostate | - Transurethral resection of prostate (TURP)<br>- Transurethral incision of the prostate (TUIP) or bladder neck<br>- Transurethral resection of bladder tumours (TURBT)<br>- Cystodiathermy<br>-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 |
| **Working element compatibility** | Storz<br>Olympus | Storz<br>Olympus | Same |
| **Sterilization of working element** | Steam sterilization<br>(autoclave) | Steam sterilization<br>(autoclave) | Same |

| | **Proposed device**<br>Plasma EDGE System (K213135) | **Predicate device**<br>Plasma EDGE System (K163090) | **Substantial Equivalence Analyis** |
|---|---|---|---|
| **MATERIALS OF ELECTRODES** | | | |
| **Active tip of thin and thick loop - WIRE** | Tungsten wire<br>99,95% | Tungsten wire<br>99,95% | Same |
| **Active wire - WIRE** | Platinum iridium | Platinum iridium | Same |
| **Insulation** | Ceramic ZTA10 | Ceramic ZTA10 | Same |
| **Wire insulation** | PTFE<br>AWG28 | PTFE<br>AWG28 | Same |
| **Heat-shrink tubing** | MT 3000 | MT 3000 | Same |
| **Skeleton** | Stainless Steel 316L | Stainless Steel 316L | Same |
| **Telescope clip** | PEEK 150G | PEEK 150G | Same |
| **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<br>ISPLEN PP 080 | Polypropylene<br>ISPLEN PP 080 | Same |
| **Connector over-moulding (FRONT load)** | Polypropylene<br>Multiflex G60 A11B | Polypropylene<br>Multiflex G60 A11B | Same |

| | **Proposed device**<br>Plasma EDGE System (K213135) | **Predicate device**<br>Plasma EDGE System (K163090) | **Substantial Equivalence Analyis** |
|---|---|---|---|
| **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<br><br>-One side PET/PE 60 Pharma (transparent) | - One side PGL 110: 100g/m² Medical Kraft Paper / 10g/m² Grid Lacquer<br><br>- One side PET/PEVA film | Any differences were validated and did not raise any new risks. |
| **Blister material** | PETG | APET CRISTAL / CAROCLEAR MDL 50 | Any differences were validated and did not raise any new risks. |
| **Packaging process** | | | |
| **Packaging Machine:** | Hawo machine Impulse heat sealer (sealing of the last side of the pouch) | Maruani machine (Sealing of 3 sides of the pouch) HAWO scroll welding (Sealing of the last side of the pouch) | Any differences were validated and did not raise any new risks. |
| **Sealing temperature:** | 127°C | 180°C (for both machine) | Any differences were validated and did not raise any new risks. |
| **Sealing speed:** | sealing time = 1,5s<br>total times = 10s (sealing dies closing – opening) | MARUANI:<br>• Up to 1500 cycles/hour<br>Hawo:<br>sealing speed: 10m/min | Any differences were validated and did not raise any new risks. |
| **Contact pressure:** | 115N<br>This parameter is not modified by LNM (only by HAWO) | MARUANI:<br>• non communicated<br>Hawo: 100N | Any differences were validated and did not raise any new risks. |

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 packaging material and packaging process did not change the technological characteristics, the design nor fundamental operating principles of modified device compared to the predicate. The modification of the packaging material and packaging 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.