November 21, 2019

US Medical Innovations, LLC
% Timothy Joiner, Senior Consultant
Emergo Global Consulting, LLC
2500 Bee Cave Road, Building 1, Suite 300
Austin, Texas 78746

Re: K192124
Trade/Device Name: Canady Plasma SMART XL-1000 Electrosurgical Generator with Accessories
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: October 22, 2019
Received: October 28, 2019

Dear Timothy Joiner:

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,

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192124

Device Name
Canady Plasma® SMART XL-1000™ Electrosurgical Generator with Accessories

Indications for Use *(Describe)*
The Canady Plasma® SMART XL-1000™ Electrosurgical Generator with Accessories is intended to provide gas-enhanced coagulation during general surgery procedures. The Canady Plasma® SMART XL-1000™ Electrosurgical Generator with Accessories is designed for gas enhanced coagulation when used only with the Canady Plasma Electrosurgery Unit and compatible monopolar and/or bipolar handpieces.

The Canady Electrosurgery Unit Generators are intended to cut and/or coagulate tissue when used with compatible monopolar and/or bipolar RF handpieces. The Canady Electrosurgery Unit Generators are capable of monopolar argon gas enhanced coagulation when used with Canady Plasma Coagulator and probes

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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Special 510(k) Summary

Canady Plasma® SMART XL-1000™ Electrosurgical Generator with Accessories

1. Submission Sponsor

US Medical Innovations, LLC
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USA
Contact: Jerome Canady
Title: CEO

2. Submission Correspondent

Emergo Global Consulting, LLC
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Austin, TX 78746
Office Phone: (512) 327-9997
Contact: Timothy Joiner
Title: Senior Consultant

3. Date Prepared

August 5, 2019

4. Device Identification

Trade/Proprietary Name: Canady Plasma® SMART XL-1000™ Electrosurgical Generator with Accessories
Common/Usual Name: Electrosurgical Generator
Classification Name: Electrosurgical cutting and coagulation device and accessories
Regulation Number: 878.4400
Product Code: GEI
Class: 2
Classification Panel: General and Plastic Surgery

5. Legally Marketed Predicate Device

Canady Plasma® Electrosurgical Unit SS Series with Accessories (K100669)

6. Indication for Use Statement

The Canady Plasma® SMART XL-1000™ Electrosurgical Generator with Accessories is intended to provide gas-enhanced coagulation during general surgery procedures. The Canady Plasma® SMART XL-1000™ Electrosurgical Generator with Accessories is designed for gas enhanced coagulation when used only with the Canady Plasma Electrosurgery Unit and compatible monopolar and/or bipolar handpieces.

The Canady Electrosurgery Unit Generators are intended to cut and/or coagulate tissue when used with compatible monopolar and/or bipolar RF handpieces. The Canady Electrosurgery Unit Generators are capable of monopolar argon gas enhanced coagulation when used with Canady Plasma Coagulator and probes.

7. Device Description

The Canady Plasma® SMART XL-1000™ Electrosurgical Generator (CPSXEG) with Accessories is a High Frequency (HF) Electrosurgery Unit (ESU) used in combination with electrosurgical probes. The CPSXEG combines (HF) voltage to electrically enhanced plasma gas (i.e. Argon) to produce a plasma gas stream. Current density upon arrival at the tissue surface from Canady Plasma Probes causes coagulation of the tissue. The CPSXEG is also a monopolar and bipolar RF surgical device for cutting and coagulation. It is used for tissue removal and coagulation in accordance with the operative procedure performed by the physician. The unit provides various cutting, coagulation, hybrid plasma, and argon plasma modes to meet the physician's flexibility performing the specific procedure with the device

The modified Canady Plasma Smart XL-1000™ ESU has the same intended use as the predicate SS-601/Argon 4 Canady Plasma® Electrosurgical Unit as well as the same performance specifications. The modified device has the same protective circuits as the predicate ESU which displays the equipment output error on the monitor screen with a graphic symbol so that the user can determine the cause of the error. The packaging, labeling (i.e. user manual) are the same.

The Canady Plasma® SMART XL-1000™ Electrosurgical Generator has a touch screen color monitor that provides the user with quick start, on screen tutorial and user manual as well as operational and settings. Various cutting, coagulation, bipolar, and plasma modes are the same as the predicate unit, but the modified device has improved programmable software. When turned on, an APPS screen is displayed on the monitor screen. The user can decide which medical application is started by touching the particular application (i.e Pediatrics, orthopedics, endoscopy, gynecology). Upon activation of the device audio and visual error system malfunctions or user errors can be observed by the user. Once the device is activated, power in watts, gas flow rate, gas volume, PPM, and energy mode are displayed on the monitor screen.

8. Substantial Equivalence Discussion

The following table compares the Canady Plasma® SMART XL-1000™ Electrosurgical Generator with Accessories to the predicate device with respect to intended use, principles of operation, technological characteristics, and performance, and forms the basis for the determination of substantial equivalence. The subject device does not raise any new questions of safety or effectiveness as compared to the predicate device.

Table 5A – Comparison of Characteristics

Trade Name	Canady Plasma Electrosurgery Unit (Predicate Device)	Canady Plasma SMART Electrosurgical Generator XL-1000	Significant Difference
Manufacturer	USMI	USMI	N/A
510(k) Number	K100669		N/A
Model	SS-601MCa	XL-1000	N/A
CPC Used With	Canady Plasma Coagulator Argon 4	CPC is consolidated into the XL-1000	N/A
Intended Use	Cut and/or coagulate tissue	Cut and/or coagulate tissue	None
Generator Type	High Frequency	High Frequency	None
Frequency	390 kHz	390 kHz	None
Peak to Peak Voltage (rated Ω)	4kV (1000 Ω)	4kV (1000 Ω)	None
Main CPU Type	FPGA	FPGA	None
Display Type	LED with backlight	LCD with backlight	Minor
Monopolar	Yes, insulated	Yes, insulated	None
Bipolar	Yes	Yes	None
Handswitch	Yes	Yes	None
Footswitch	Yes, independent switches for monopolar and bipolar	Yes, independent switches for monopolar and bipolar	None
Monopolar Modes	Cut (Pure, Blend I,II,III, Pure High Cut, Blend High Cut I,II), E-Cut Coagulation (Spray, Fulgurate High, Fulgurate Low, Desiccate I,II,III)	Cut (Pure, Blend I,II,III, Pure High Cut, Blend High Cut I,II), E-Cut Coagulation (Spray, Fulgurate High, Fulgurate Low, Desiccate I,II,III)	None
Bipolar Modes	Cut, Coagulate (Micro, Default, Macro)	Cut, Coagulate (Micro, Default, Macro)	None
Volume Control	Yes	Yes	None
Defeatable-Inaudible Volume Control	No	No	None
Power Setting Shown	Yes	Yes	None
Cooling Type	Convection	Convection	None
Input Voltage, VAC	100 – 240	100 – 240	None
Meets IEC 60601-1	Yes	Yes	None
Meets IEC 60601-1-2	Yes	Yes	None
Meets IEC 60601-2-2	Yes	Yes	None

9. Non-Clinical Performance Data

Internal verification and validation testing confirm that product specifications of the Canady Plasma® SMART XL-1000™ Electrosurgical Generator with Accessories are met. These are equivalent to those of the unmodified predicate device. The testing/measurement of the output parameters of the Canady Plasma® SMART XL-1000™ Electrosurgical Generator (CPSEG-XL-1000) was performed to demonstrate that the CPSEG-XL-1000 performed as specified and in accordance with the specifications of the predicate device USMI SS-601/Argon 4. The results support that the device's design changes do not affect the safe and effective use of the device as compared to the unmodified predicate device.

US Medical Innovations, LLC established design and development quality system procedures to direct and control hardware and software design and development activities. The following procedures are: Development plan, design, Design input / Software (as applicable) Risk Management/ Risk Analysis, Design Review, Validation Master Sheet, Verification Master Sheet, Design Change Master Sheet, Design Transfer Checklist and Release Documentation. The activities provide a framework for final project and management approval for the necessary controls on the design and development of new products.

The Canady Plasma® SMART XL-1000™ Electrosurgical Generator with Accessories has the same principles of operation and technological characteristics as the predicate device in the previous 510k (K100669).

Electromagnetic Compatibility, Electrical Safety, and Performance Testing of the Canady Plasma® SMART XL-1000™ Electrosurgical Generator with Accessories included the following testing:

EM / ES	**Performance**	**Usability**
Conducted Emissions - Voltage	Crest Factor Comparison	Operation Modes Selection Test
Radiated Emissions	Frequency	Power Adjustment Test
Harmonic Current Emission	Peak to Peak Voltage	Flow Rate Adjustment Test
Voltage Fluctuations / Flicker	Monopolar Cut Mode	Standby Mode System Activation Test
Radiated Electromagnetic Field Immunity	Maximum Watts	Gas Tank Pressure Value Indication Test
Immunity to Proximity Fields from RF Wireless Communications Equipment	Maximum Voltage	Audio / Visual Warning / Notification Test
Surge Immunity	Bipolar Cut Mode	User Profile Selection Test
Conducted RF Immunity	Maximum Watts	User Profile Editing Test
Magnetic Immunity	Maximum Voltage	Font Size Visibility Test
Voltage Dips Interruption and Variations		Icon Size Visibility Test
		Button Response Test
		Font / Icon Color Code Test
		Power Button Increment / Decrement Speed Test
		Power Mode Icon Graphic Visibility Test
		Patient Pad Connectivity Notification / Alarm Test
		Touchscreen EMF Immunity Test
		LCD Brightness Visibility Test
		Audio Volume Adjustment Test
		Multitouch Prevention Test
		Glove Test
		Liquid Spill Test
		Touchscreen LED Test
		Touchscreen Impact Test
		Chemical Resistance Test

10. Statement of Substantial Equivalence

The Canady Plasma® SMART XL-1000™ Electrosurgical Generator with Accessories has the same intended use as the predicate device, and the same or similar technological characteristics. The modifications in technological characteristics do not raise new or different questions of safety and effectiveness. Performance testing in accordance with standards has demonstrated the Canady Plasma® SMART XL-

1000™ Electrosurgical Generator with Accessories is as safe and effective as the predicate device. Therefore, the Canady Plasma® SMART XL-1000™ Electrosurgical Generator with Accessories is substantially equivalent to the Canady Plasma® Electrosurgical Unit SS Series with Accessories.