May 3, 2024

US Medical Innovations, LLC
% Audrey Swearingen
Sr. Regulatory Consultant
Emergo Global Consulting, LLC
2500 Bee Cave Road
Building 1, Suite 300
Austin, Texas 78746

Re: K240297
Trade/Device Name: Canady Helios Cold Plasma™ XL-1000CP™ Ablation System (XL-1000CPSYS)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: February 1, 2024
Received: February 1, 2024

Dear Audrey Swearingen:

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 Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2024.05.03 11:01:07 -04'00'

Mark Trumbore, 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240297

Device Name

Canady Helios Cold Plasma™ XL-1000CP™ Ablation System (XL-1000CPSYS)

Indications for Use *(Describe)*

The Canady Helios Cold Plasma™ XL-1000CP™ Ablation System is indicated for the gas enhanced ablation of soft tissue using helium-based plasma.

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.

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510(k) Summary

Canady Helios Cold Plasma™ XL-1000CP™ Ablation System

The following information is provided in accordance with 21 CFR 807.92.

Submission Sponsor:

US Medical Innovations LLC
6930 Carroll Avenue, Suite 1000
Takoma Park, MD 20912
Contact: Jerome Canady, MD., FACS
Title: CEO
Phone: (301) 270-0147

Submission Correspondent:

Emergo by UL
2500 Bee Cave Road, Building 1, Suite 300
Austin, TX 78746
Contact: Ms. Audrey Swearingen
Title: Senior Regulatory Consultant
Phone: (512) 327-9997
Email: LST.AUS.ProjectManagement@ul.com

Date: April 18, 2024

Device Identification:

Trade or Proprietary Name:	Canady Helios Cold Plasma™ XL-1000CP™ Ablation System (XL-1000CPSYS)
Common or Usual Name:	Surgical ablation system
Regulation Number:	21 CFR 878.4400
Regulation Name:	Electrosurgical cutting and coagulation device and accessories
Product Code:	GEI
Device Class:	II
Panel:	General & Plastic Surgery

Legally Marketed Predicate Device:

Trade Name:	Canady Plasma SMART XL-1000 Electrosurgical Generator with Accessories
510(k) Number:	K192124
Manufacturer:	US Medical Innovations LLC
Regulation Number:	21 CFR 878.4400
Regulation Name:	Electrosurgical cutting and coagulation device and accessories
Product Code:	GEI

Intended Use/Indications for Use:

The Canady Helios Cold Plasma™ XL-1000CP™ Ablation System is indicated for the gas enhanced ablation of soft tissue using helium-based plasma.

Device Description:

The Canady Helios Cold Plasma™ XL-1000CP™ Ablation System produces a Helium-based cold plasma spray to deliver high frequency low energy current intended for the ablation of soft tissues.

The Canady Helios Cold Plasma™ XL-1000CP Ablation System includes the following items:

- Canady Helios Cold Plasma™ XL-1000CP SMART Electrosurgical Generator
- Canady Helios™ Cold Plasma Ablators
- Foot Pedal
- Trolley Cart

The Canady Helios Cold Plasma™ XL-1000CP™ SMART Electrosurgical Generator is a transportable non-sterile electrical device compatible for use in the operating room environment. The Canady Helios Cold Plasma™ XL-1000CP SMART Electrosurgical Generator creates high frequency, short duration energy pulses with regulated Helium gas, which is delivered to the target tissue via the Canady Helios™ Cold Plasma Ablators. The Canady Helios™ Cold Plasma Ablators are sterile monopolar electrosurgical instruments intended for single use.

Substantial Equivalence:

The following table compares the proposed Canady Helios Cold Plasma™ XL-1000CP™ Ablation System to the Canady Plasma SMART XL-1000 Electrosurgical Generator with Accessories predicate device, with respect to intended use and technological characteristics.

Trade Name	**Canady Helios Cold Plasma™ XL-1000CP™ SMART Ablation System**	**Canady Plasma SMART XL-1000 Electrosurgical Generator with Accessories System** (K192124)	**Significant Difference**
Manufacturer	US Medical Innovations, LLC	US Medical Innovations, LLC	N/A
Product code(s)/ Regulation No.	GEI / 878.4400	GEI / 878.4400	Both are under the same regulation
Intended Use	Gas enhanced ablation of soft tissue.	Gas enhanced ablation of soft tissue.	None
Indications for Use	The Canady Helios Cold Plasma™ XL-1000CP™ SMART Ablation System is indicated for gas enhanced ablation of soft tissue using helium based plasma.	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	The XL-1000CP uses a subset of the Indications for use defined for the predicate device.

		handpieces. **The Canady Electrosurgery Unit Generators are capable of monopolar argon gas enhanced coagulation when used with Canady Plasma Coagulator and probes**.	
System Components	• Canady Helios Cold Plasma™ XL-1000CP™ SMART Electrosurgical Generator • Canady Helios™ Cold Plasma Ablators • Footswitch • Power Supply Cord • XL-1000/XL-1000CP Trolley Cart	• Canady Plasma® SMART XL-1000™ Electrosurgical Generator • Canady Plasma Hybrid Scalpel (K113500) • Canady Plasma Probes for Flexible Endoscopy (K100669) • Footswitch • Power Supply Cord • XL-1000/XL-1000CP Trolley Cart	Same. The subject Ablators are identical to the predicate's handpieces.
Generator Type	High Frequency	High Frequency	None
Inert Gas Type	Helium	Argon	The XL-1000CP uses the inert gas Helium instead of Argon.
Frequency	390 kHz	390 kHz	None
Peak to Peak Voltage	4kV (1000 Ω)	4kV (1000 Ω)	None
Main CPU Type	FPGA	FPGA	None
Display Type	LED with backlight	LED with backlight	None
Monopolar	Yes, insulated	Yes, insulated	None
Bipolar	No	Yes	The XL-1000CP generator only supports monopolar ablation.
Monopolar Modes	Canady Helios Cold Plasma Ablation Mode (equivalent to Fulgurate High on the XL-1000)	Argon Plasma - Cut (Pure, Blend I,II,III, Pure High Cut, Blend High Cut I,II), E-Cut, Argon Plasma (Spray, Fulgurate High, Fulgurate Low, Desiccate I,II,III)	Cold Plasma ablation mode is the same as the Argon Plasma Fulgurate High mode of the XL-1000.
Gas Flow Rate	0.0 - 5.0 L/min	0.0 - 5.0 L/min	None
Power Setting Shown	Yes	Yes	None
Cooling Type	Convection	Convection	None
Input Voltage, VAC	100 – 240	100 – 240	None
Performance	Shown to ablate soft tissue at specified parameters.	Shown to ablate soft tissue at specified parameters.	Both perform as intended to ablate soft tissue.

Performance Testing:

The following tests were conducted to confirm that the Canady Helios Cold Plasma™ XL-1000CP™ Ablation System meets specifications and that it performs equivalently to the predicate Canady Plasma SMART XL-1000 Electrosurgical Generator with Accessories.

Electrical Safety Testing	Met criteria
High Frequency Testing	Met criteria
Electromagnetic Compatibility Testing	Met criteria
Electromechanical Safety Testing	Met criteria
Package Integrity	Met criteria
Shelf Life	Met criteria
Sterilization	Met criteria
Software and System Verification / Validation	Met criteria
Cybersecurity	Met criteria
Biological Safety	Met criteria
Ablation Effectiveness	Met criteria
Thermal Effect	Met criteria

The device complies with the following applicable test standards:

ANSI/AAMI/ISO 11135: 2014/AMD 2018	Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices
ANSI/AAMI/ISO 11737-1:2018	Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products
ANSI/AAMI/ISO 11737-2 2019	Sterilization of medical devices — Microbiological methods — Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
AAMI/ANSI ES 60601-1:2005/2012	Medical Electrical Equipment - Part 1 General Requirements for Basic Safety and Essential Performance
IEC 60601-1-2:2020	Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests
IEC 60601-2-2:2017 Edition 6.0	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 60601-1-6:2010+AMD1:2013	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 62304 Ed 1.1 2015-06, Consol. version	Medical device software – Software life cycle processes

Conclusion:

The Canady Helios Cold Plasma™ XL-1000CP™ Ablation System has the same intended use and the same or similar technological characteristics as the predicate device. Testing to recognized consensus standards and internal performance testing has demonstrated the device is as safe and effective for requested intended use, as the predicate device. The minor technological differences compared to the predicate do not raise different types of questions of safety and effectiveness. Therefore, the Canady Helios Cold Plasma™ XL-1000CP™ Ablation System is substantially equivalent to the predicate device.