January 7, 2020

Cambridge Interventional LLC
Michael Arnold
President
78 Cambridge Street
Burlington, Massachusetts 01803

Re: K192715
Trade/Device Name: CRF Radiofrequency Ablation System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: November 12, 2019
Received: November 19, 2019

Dear Michael Arnold:

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 and Part 809); 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)*
K192715

Device Name

CRF Radiofrequency Ablation System

Indications for Use *(Describe)*

The CRF Radiofrequency Ablation System is indicated for use in percutaneous, laparoscopic and intraoperative coagulation and ablation of tissue.

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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CAMBRIDGE
INTERVENTIONAL

510(k) Summary

CRF Radiofrequency Ablation System

Submitter:
Cambridge Interventional LLC
78 Cambridge Street
Burlington MA 01803

Telephone: 617-365-6899
Contact Name: Michael Arnold
Email: marnold@cambint.com

Date prepared: November 12, 2019

Device Name and Classification
Model Name: CRF Radiofrequency Ablation System
Common Name: Electrosurgical Cutting and Coagulation Device and Accessories
Classification Name: Electrosurgical, Cutting & Coagulation & Accessories
Regulation Number: 21 CFR 878.4400
Product Code: GEI
Device Class: II

Name of Predicate Device
Valleylab Cool-tip™ Switching Controller (K070446) - Product Code GEI, Class II

Name of Reference Device
Valleylab Cool-tip™ Radiofrequency Ablation System (K052796) - Product Code GEI, Class II

Description of Device
The CRF Radiofrequency Ablation System consists of an RF generator, active electrode, grounding pad, tubing set, and peristaltic pump for electrode cooling. This device is designed to produce local tissue heating at the tip of the electrode causing coagulation and ablation of tissue. The CRF Generator supplies radiofrequency energy at 480 kHz while monitoring both the tissue impedance and temperature at the CRF electrode tip. The CRF Generator monitors the power, resistance, current and temperature during energy delivery to the patient.

The CRF Electrodes are sterile, single-use, hand-held devices designed for use in radiofrequency ablation procedures. The electrodes are surgically invasive, transient devices in patient contact typically for less than one hour. Cooling of the electrodes is provided by chilled sterile saline or water that is pumped through the inflow tubing, the electrode and out via outflow tubing. This is an enclosed system within the electrode and the saline does not contact the patient. The CRF Generator automatically monitors impedance and temperature and adjusts RF output accordingly. The CRF Radiofrequency Ablation System is used in a healthcare facility or hospital setting. The table below lists components for the CRF Radiofrequency Ablation System.

Catalog No.	Description of Component	Provided Sterile?
CRF	CRF Radiofrequency Generator	No
CRF-C1020	RF Cannula, 10 cm, 2 cm Tip	Yes
CRF-C1030	RF Cannula, 10 cm, 3 cm Tip	Yes
CRF-C1510	RF Cannula, 15 cm, 1 cm Tip	Yes
CRF-C1520	RF Cannula, 15 cm, 2 cm Tip	Yes
CRF-C1530	RF Cannula, 15 cm, 3 cm Tip	Yes
CRF-C2020	RF Cannula, 20 cm, 2 cm Tip	Yes
CRF-C2030	RF Cannula, 20 cm, 3 cm Tip	Yes
CRF-C2040	RF Cannula, 20 cm, 4 cm Tip	Yes
CRF-C2050	RF Cannula, 20 cm, 5 cm Tip	Yes

Catalog No.	Description of Component	Provided Sterile?
CRF-C2520	RF Cannula, 25 cm, 2 cm Tip	Yes
CRF-C2530	RF Cannula, 25 cm, 3 cm Tip	Yes
CRF-E10	RF Electrode, Cooled, Blunt Tip, 10 cm	Yes
CRF-E15	RF Electrode, Cooled, Blunt Tip, 15 cm	Yes
CRF-E20	RF Electrode, Cooled, Blunt Tip, 20 cm	Yes
CRF-E25	RF Electrode, Cooled, Blunt Tip, 25 cm	Yes
CRF-N1005	RF Electrode, Non-Cooled, Sharp Tip, 10cm, 0.5cm Tip	Yes
CRF-N1510	RF Electrode, Non-Cooled, Sharp Tip, 15cm, 1cm Tip	Yes
CRF-N2020	RF Electrode, Non-Cooled, Sharp Tip, 20cm, 2cm Tip	Yes
CRF-N2520	RF Electrode, Non-Cooled, Sharp Tip, 25cm, 2cm Tip	Yes
CRF-TN	Temperature Probe, Cannula	Yes
CRF-TP	Temperature Probe, Blunt Probe	Yes
CRF-U1020	RF Electrode, Cooled, Sharp Tip, 10cm, 2cm Tip	Yes
CRF-U1030	RF Electrode, Cooled, Sharp Tip, 10cm, 3cm Tip	Yes
CRF-U1507	RF Electrode, Cooled, Sharp Tip, 15cm, 0.7cm Tip	Yes
CRF-U1510	RF Electrode, Cooled, Sharp Tip, 15cm, 1cm Tip	Yes
CRF-U1520	RF Electrode, Cooled, Sharp Tip, 15cm, 2cm Tip	Yes
CRF-U1530	RF Electrode, Cooled, Sharp Tip, 15cm, 3cm Tip	Yes
CRF-U2020	RF Electrode, Cooled, Sharp Tip, 20cm, 2cm Tip	Yes
CRF-U2030	RF Electrode, Cooled, Sharp Tip, 20cm, 3cm Tip	Yes
CRF-U2050	RF Electrode, Cooled, Sharp Tip, 20cm, 5cm Tip	Yes
CRF-U2525	RF Electrode, Cooled, Sharp Tip, 25cm, 2.5cm Tip	Yes
CRF-U2535	RF Electrode, Cooled, Sharp Tip, 25cm, 3.5cm Tip	Yes
CRF-FS	Footswitch	No
CRF-PUMP	Pump	No
CRF-A3E	Cable, CRF electrodes to CRF generator	No
CRF-AME	Cable, CRF electrode to Cool-tip generator	No
CRF-AMG	Cable, CRF-GP to Cool-tip generator	No
CRF-SCG	Storage Case for CRF Generator	No
CRF-SCP	Storage Case for Pump	No
CRF-TUBE	Tubing Set for Pump	Yes
CRF-GBC	Introducer for CRF-C	Yes
CRF-GBU	Introducer for CRF-U	Yes
CRF-GP	Ground Pad, Disposable	No

Indications for Use

The CRF Radiofrequency Ablation System is intended for use in percutaneous, laparoscopic, intraoperative coagulation and ablation of tissue.

The Indications for Use statement is consistent with the predicate Cool-tip™ device, but without specific indications.

Comparison to Predicate Device

Compared to the predicate Cool-tip™ device, the CRF Radiofrequency Ablation System has similar technological characteristics and operating principle. There are no significant design or performance specifications that affect safety or effectiveness of the subject device. There is substantial equivalence between the subject device and the predicate with respect to indications and intended use. The CRF Radiofrequency Ablation System is substantially equivalent to the legally marketed predicate device with respect to indications for use and technology characteristics. The table below presents side-by-side comparisons for each major component for the subject and predicate device.

Parameter	Subject Device	Predicate Device	Comparison
Device	CRF Radiofrequency Ablation System	Valleylab Cool-tip™ Switching Controller (K070446)	N/A
Indication	The CRF Radiofrequency Ablation System is indicated for use in percutaneous, laparoscopic and intraoperative coagulation and ablation of tissue.	The Cool-tip™ RF Switching Controller is to be used with the Cool-tip™ RF System and is intended for use in percutaneous, laparoscopic and intraoperative coagulation and ablation of tissue, such as partial or complete ablation of nonresectable liver tumors, and osteoid osteoma tumors within bone.	Different
Principle of Operation	Provide RF energy to patient-contacting TC Electrode for tissue ablation.	Provide RF energy to patient-contacting TC Electrode for tissue ablation.	Identical
Classification	878.4400	878.4400	Identical
Device Class	GEI	GEI	Identical
Generator Electrical Classification	Class 1, IPX0, Type BF	Class 1, IPX0, Type BF	Identical
Generator Output Frequency	480 kHz	480 kHz	Identical
Generator waveform	Sine wave	Sine wave	Identical
Generator waveform crest factor	1.4	1.4	Identical
Generator Rated Power	Up to 370w	Up to 200w	Different
Generator Impedance	Up to 1000 ohms	Up to 1000 ohms	Identical
Generator Timer	Up to 15:00 min	Up to 30:00 min	Different
Generator Temperature Monitor	Thermocouple	Thermocouple	Identical
Generator Footswitch control	Available	Available	Identical
TC Electrode length	10, 15, 20, 25cm	10, 14.4, 15, 20, 25cm	Different
TC Electrode tip exposure	0.5, 0.7, 1, 2, 2.5, 3, 3.5, 4, 5cm	0.7, 1, 2, 2.5, 3, 4cm	Different
TC Electrode tip diameter	0.9, 1.5, 1.8mm	1.5mm	Different
TC Electrode Cooling Mechanism	Electrode cooling is provided by sterile water, which is pumped through the inflow tubing into the Electrode shaft, and out through the outflow tubing.	Electrode cooling is provided by sterile water, which is pumped through the inflow tubing into the Electrode shaft, and out through the outflow tubing.	Identical
Maximum number of Electrodes connected simultaneously	Up to 3	Up to 3	Identical
Temp probe sensor	Type T Thermocouple	Type T Thermocouple	Identical
Temp Probe & Introducer length	20cm	20cm	Identical
Temp Probe & Introducer diameter	0.9, 1.3mm	0.9, 1.3mm	Identical
Active electrode material	Stainless Steel	Stainless Steel	Identical
Electrode insulation material	Polyester	Polyester	Identical
Electrode sterilization	ETO Sterilization	ETO Sterilization	Identical
Electrode shelf life	4 years	4 years	Identical
Electrode usage	Single Use	Single Use	Identical
Pump type	Peristaltic pump	Peristaltic pump	Identical
Pump specification	80-120 ml/min	80-140 ml/min	Different
Tubing Set Configuration	Two-piece set (inflow and outflow components)	Two-piece set (inflow and outflow components)	Identical
Tubing Set Material	PVC tubing	PVC tubing	Identical
Tubing Set sterilization	ETO Sterilization	ETO Sterilization	Identical
Tubing Set shelf life	4 years	4 years	Identical
Tubing Set usage	Single Use	Single Use	Identical
Ground Pad material	Conductive hydrogel	Conductive hydrogel	Identical
Ground Pad usage	Single Use	Single Use	Identical
Ground Pad shelf life	2 years	2 years	Identical
Ground Pad regulatory clearance	510(k) clearance (K000079)	510(k) clearance (K030697)	Identical

Summary of Non-Clinical Data

Performance testing of the device was completed to demonstrate substantial equivalence of the CRF Radiofrequency Ablation System to the identified predicate device. Non-clinical animal testing of the device was not required to establish substantial equivalence. The device components were subjected to the following verification and validation testing, as required:

• **Mechanical testing:** Mechanical verification testing was performed on subject devices to ensure compliance with current IEC 60601-1 and IEC 60601-2-2 standards and the Company's internal test requirements.

• **Electrical testing:** Electrical verification testing was conducted for the subject device to ensure compliance with current IEC 60601-1 and IEC 60601-2-2 electrical requirements.

• **Electromagnetic compatibility:** Electromagnetic compatibility testing was completed for the subject device to ensure compliance with the current IEC 60601-1-2 standard.

• **Benchtop ablation testing.** Comparative ablation verification testing was performed using an *ex vivo* tissue model to demonstrate the substantially equivalent ablation performance of the subject and predicate devices.

• **Usability testing:** Testing was performed to verify and validate the usability requirements of the subject devices as a system in compliance with IEC 62366 and IEC 60601-1-6. Elements captured included normal use errors, unanticipated use errors, and testable requirements for primary operating functions and frequent use scenarios.

• **Biocompatibility testing**: Biocompatibility testing of patient contacting CRF devices was performed in accordance with the FDA Guidance, "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"" including cytotoxicity, sensitization, systemic toxicity and irritation testing. All CRF devices demonstrated compliance with listed requirements.

• **Sterilization validation testing:** ETO sterilization validation for CRF devices was carried out using the overkill method and half-cycles in accordance with the current ISO 11135 standard to provide a SAL of 10^{-6}.

• **Packaging and shelf life testing:** Sterile packaging performance testing was conducted for the subject devices in their final packaging. Shelf life testing for sterile subject devices and packaging was conducted based on an accelerated aging protocol in accordance with ASTM F1980-16, the standard guide for accelerated aging of sterile barrier systems for medical devices. Real-time age testing will be performed to add to and support the results of the accelerated age testing.

• **Software validation testing:**
The CRF radiofrequency generator includes software developed according to the Company's software development process in compliance with the current IEC 62304 standard. Software verification and validation testing was conducted in accordance with the FDA Guidance for Content of Premarket Submissions for Software Contained in Medical Devices (2005) and IEC 62304.

Summary of Clinical Data

Clinical testing of the device was not required to establish substantial equivalence.

Conclusion

The CRF Radiofrequency Ablation System is substantially equivalent to the predicate device cleared in K070446. The subject and predicate devices share the same fundamental scientific technology, including principles of operation and mechanism of action. Differences in design and technological characteristics between the subject device and predicate device do not raise any new questions of safety and effectiveness. The intended use of the subject device has not changed. The comparison of technological characteristics, non-clinical performance data, electrical safety and electromagnetic compatibility testing demonstrates that the CRF Radiofrequency Ablation System is substantially equivalent to the previously cleared predicate device.