February 25, 2022

Covidien LLC
Liron Bar yaakov
Senior Manager, Regulatory Affairs
5920 Longbow Drive
Boulder, Colorado 80301

Re: K203150
Trade/Device Name: Cool-tip RF Ablation System E Series
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: January 19, 2022
Received: January 21, 2020

Dear Liron Yaakov:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203150

Device Name
Cool-tip RF Ablation system E Series

Indications for Use *(Describe)*
The Cool-tip RF Ablation System E Series (generator, pump, patient return electrodes, water container, active electrodes, footswitch, and accessories) is intended for use in percutaneous, laparoscopic, and intraoperative coagulation and ablation of tissue, including partial or complete ablation of non-resectable liver tumors.

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

1. Date of Summary Preparation

February 24, 2022

2. 510(k) Submitter/Holder

Covidien llc

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4. Device

Device Trade Name:	Cool-tip™ RF Ablation System E Series
Device Common Name:	RF Ablation System
Classification Name:	Electrosurgical Cutting and Coagulation Device and Accessories
Regulation:	21 CFR 878.4400
Regulatory Class:	II
Product Code:	GEI

5. Predicate Device

The Cool-tip™ RF Ablation System E Series is substantially equivalent to the following, commercially available predicate devices:

Device Name	Classification Name and Class	510(k) Number(s)
Cool-tip™ RF Ablation Generator	Electrosurgical, Cutting & Coagulation & Accessories	K052796 (Primary Predicate Device)
Cool-tip™ Switching Controller	Electrosurgical, Cutting & Coagulation & Accessories	K070446

6 Intended Use / Indications for Use

The Covidien Cool-tip™ RF Ablation System E Series (generator, pump, patient return electrodes, water container, active electrodes, footswitch, and accessories) is intended for use in percutaneous, laparoscopic, and intraoperative coagulation and ablation of tissue, including partial or complete ablation of non-resectable liver tumors.

6.1 Indication Difference from the Predicate Device

The indication of “osteoid osteoma tumors within bone” has been removed from the subject device.

This change is not critical to the intended therapeutic, diagnostic, prosthetic or surgical use of this device and does not affect the safety and effectiveness of the device when used as labeled.

7. Device Description

The Cool-tip™ RF Ablation System E Series (subject device) is a monopolar radio-frequency (RF) generator (RFAGEN) with dedicated components and accessories. The RFAGEN generator can be operated in one of several modes that use various combinations of time, tissue temperature, tissue impedance, and manual control. An interactive touchscreen display allows user input to the generator and displays informational signals and alert messages. Active electrodes are placed in the tissue to deliver RF energy to the tissue to be ablated. One, two, or three active electrodes can be attached to the generator and can be used individually or as multiple depending on electrode type and mode. A cluster electrode with 3 electrodes assembled into one hub in a triangular pattern can also be used. During the ablation of tissue, RF current flows from the generator to an active electrode which delivers the current to the patient. The RF current flows from the active electrode through the patient’s body tissue to the return electrode, which recovers the current and returns it to the generator. The resistance to the current, provided by the patient’s tissue, produces the heat that is necessary for ablation of tissue, including partial or complete ablation of non-resectable liver tumors.

A peristaltic pump circulates sterile cooling water from an I.V. bag, through active electrodes and into a wastewater container. Cooling water does not contact the patient and is not recirculated. The system does not provide fluids to or remove fluids from the patient.

The dedicated system components include:

- RF Generator (RFAGEN), radio frequency generator
- RF Ablation Pump (RFAPUMP), peristaltic pump for circulating cooling water
- RF Ablation Connector Bank (RFACB) cable for connecting return electrodes to the generator
- Ablation Foot Switch (RFASW), generator footswitch
- Ablation Water Container (RFAWC), wastewater collection container

The RFAGEN generator is packaged individually and is always supplied with the accessory kit RFAPAC (separately packaged) which contains items RFAPUMP, RFACB, RFASW, and RFAWC.

The following Cool-tip™ RF Ablation System E Series compatible accessories are single use:

- RF Ablation Single Electrode Kits E Series (RFAXXXX), RF Ablation Multiple Electrode Kits E Series (RFAXXXXX), and RF Ablation Cluster Electrode Kits E Series (RFACXXXX)
- RF Ablation Patient Return Electrode E Series (RFAPAD)
- Ablation Remote Temperature Probe (RTP20) (optional)

The Cool-tip™ RF Ablation System E Series can be mounted on an optional system cart FT900RFA with the FT3X cart kit that has locations for each system component.

8. Comparison of Technological Characteristics with the Predicate Device

The Cool-tip™ RF Ablation System E Series (subject device) relies on the same principles of operation and has similar performance characteristics, with respect to its intended use, as the predicate devices. The Cool-tip™ RF Ablation System E Series combines the functional characteristics of the predicate Cool-tip™ generator (K052796) and the Cool-tip™ Switching Controller (K070446).

There are three main differences between the Cool-tip™ RF Ablation System E Series and the predicate Cool-tip™ RF Ablation System

1. A new larger patient return electrode (RFAPAD) allowing for two return electrodes for ablations where four electrodes are required for the predicate device. The return electrode connector bank (RFACB) is a new dedicated reusable extension cable that connects the patient return electrodes to the generator.
2. The RFAGEN generator combines the functional characteristics of both the predicate Cool-tip™ generator and the Cool-tip™ Switching Controller into a single RF generator that includes an updated user interface and software controls.
3. The addition of several optional accessories, specifically, a footswitch, remote temperature probe and system cart.

Like the predicate device, the Cool-tip™ RF Ablation E Series System has three categories of Cool-tip™ RF Ablation electrodes. The categories are single, multiple and cluster electrodes. The Cool-tip™ E Series active electrodes deliver RF energy from the Cool-tip™ E Series generator for the ablation of tissue when used with the Cool-tip™ E Series Pump, Inflow and Outflow Tubing Sets, and RFAPAD Patient Return Electrodes. All Cool-tip™ RF Ablation E Series are provided in kits containing sterile active electrodes, sterile tubing for electrode cooling fluid, and patient return electrodes. Electrode Kits with single, multiple and cluster active electrodes are available. All kit items are single use.

9. Performance Testing

Non-clinical performance testing was performed, and reports are provided in support of substantial equivalence with the predicate device.

9.1 Summary of Bench Testing

Electrical Safety and Electromagnetic Compatibility (EMC):

Bench testing and verification were conducted to ensure proper device function. At the system level, electrical safety and electromagnetic compatibility were evaluated to establish conformity to the applicable IEC 60601 safety standards, as identified below.

- IEC 60601-1:2005/AMD1:2012 Medical Electrical Equipment Part 1 General Requirements for Basic Safety and Essential Performance
- IEC 60601-1-2:2014 (4th Edition) Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements and Tests
- IEC 60601-1-6:2010, AMD1:2013 General Requirements for Basic Safety and Essential Performance Safety - Collateral Standard: Usability
- IEC 60601-2-2:2017 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

The performance and safety of the Cool-tip™ RF Ablation System E Series was characterized using laboratory (bench) verification and simulated-use validation testing consisting of soft tissue performance providing a characterization of the E Series system ablation performance across the complete range of modes, electrodes, and in three tissue types: liver, kidney, and muscle. Ablation performance verifying the equivalence between the predicate Cool-tip™ RFA System and the Cool-tip™ RF Ablation System E Series when used with the Cool-tip™ RF Ablation Electrode Kits E Series was performed at the system and sub-system level to demonstrate the following:

- Cool-tip™ E Series RF Ablation Generator meets all design and performance requirements necessary to prove substantial equivalence with the predicate device,
- Cool-tip™ E Series RF Ablation Generator meets all ablation performance design requirements and to demonstrate the ablations zone dimensions created with the Cool-tip™ E Series Ablation Generator (subject) and Cool-tip™ RF Ablation Generator (predicate) are equivalent,
- The previously cleared accessories (remote temperature probe and footswitch) are compatible with the Cool-tip™ E Series Ablation Generator (RFAGEN),
- The RF Ablation Patient Return Electrode E Series (RFAPAD), peristaltic pump (RFAPUMP), and RF Ablation Connector Bank (RFACB) cable meet design and performance requirements,
- The Cool-tip™ RF Ablation System E Series with Ablation Generator meets IEC, EMC, regulatory and safety requirements,
- The Cool-tip™ E Series RF Ablation System E and optional Cart (FT900RFA) performs as specified within specified storage and use conditions,
- Validate the usability of Cool-tip™ RF Ablation System E Series Ablation Generator (RFAGEN) with the intended users,
- The Cool-tip™ E Series RF Ablation Generator (RFAGEN), Patient Return Electrode (RFAPAD), RF Ablation Single Electrode Kits E Series (RFAXXXX), RF Ablation Multiple Electrode Kits E Series (RFAXXXXX), and RF Ablation Cluster Electrode Kits E Series (RFACXXXX), and Cart (FT900RFA) packaging can provide protection during simulated transportation.

9.2 Animal Testing

In-vivo testing conducted demonstrated the histological, thermal and ablative performance , as well as procedural safety of the subject device is equivalent to the predicate for the Cool-tip™ E Series intended use.

9.3 Clinical Testing

Clinical studies in human subjects were not required to demonstrate the performance and safety of the Cool-tip™ RF Ablation System E Series generator and accessories.

10. Software

Software for the Cool-tip™ RF Ablation System E Series was developed in accordance with IEC 62304 Medical device software life-cycle practices and FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, for devices with a Major Level of Concern. System level software testing was completed successfully (SW version1.41.01).

11. Biocompatibility

The direct patient contacting devices of the Cool-tip™ RF Ablation System E Series are the patient return electrode, active electrode and remote temperature probe. These devices are disposable and intended for single use. These devices were assessed for biocompatibility and potential adverse health effects associated with patient contacting disposable devices and were determined to be acceptable.

Direct Patient Contacting Devices;

Patient Return Electrode (RFAPAD):

The RFAPAD is used to collect the RF energy delivered at the active electrode and return it to the generator.

The patient contacting materials in the RFAPAD patient return electrode were tested to the biocompatibility requirements shown below.

- Cytotoxicity
- Sensitization
- Irritation or Intracutaneous Reactivity
- Materials Mediated Pyrogenicity

Active Electrode:

Active electrodes are placed in the tissue to deliver RF energy to the tissue being ablated.

The patient contacting materials in the Active Electrode were tested to the biocompatibility requirements shown below:

- Cytotoxicity Test
- Sensitization Test
- Intracutaneous Irritation Test
- Acute Systemic Toxicity Test
- Materials Mediated Pyrogenicity

Remote Temperature Probe (RTP20):

The RTP20 is an optional single use sterile device used to determine the temperature of tissue near the treatment site.

The patient contacting materials in the Remote Temperature Probe were tested to the biocompatibility requirements shown below.

- Cytotoxicity Test
- Sensitization Test
- Intracutaneous Irritation Test
- Acute Systemic Toxicity Test
- Materials Mediated Pyrogenicity Test

12. Sterilization and Shelf life

The active electrode and optional remote temperature probe are provided sterile with EtO with SAL of 10^{-6}, are intended for use within the sterile field, and are designed for single use only.

Active Electrode and Inflow and Outflow Tubing:
The sterile active electrodes and inflow/outflow tubing are identical to the previously cleared devices (K052796, K070446). The Cool-tip™ RF Ablation System E Series electrodes, inflow and outflow tubing sets are packaged together and sterilized with EtO to a sterility level of 10^{-6}. The sterile packaging is labeled as sterile for five years immediately following the date of packaging.

The single use patient return electrode are not provided sterile and have a shelf life of three (3) years.

Remote Temperature Probe:

The RTP20 used on the Cool-tip™ RF Ablation System E Series is identical to the device previously cleared with the Emprint Ablation System (K133821). The RTP20 is a sterile single use device, sterilized with EtO to a sterility level of 10^{-6}, and labeled with three (3) years shelf life.

13. Conclusion

The Cool-tip™ RF Ablation System E Series (subject device) and Cool-tip™ RF Ablation System (predicate device) have equivalent power and ablation performance characteristics based on verification and validation testing, and pre-clinical studies. Verification testing of the optional accessories consisting of the system cart, the footswitch, and remote temperature probe was conducted for their use with the subject device. As a result, the Cool-tip™ RF Ablation System E Series has been shown to be substantially equivalent to the predicate device and does not raise different questions of safety and effectiveness.