March 28, 2024

Medtronic, Inc
Steve Pavlik
Principal Regulatory Affairs Specialist
200 Medtronic Dr
Lafayette, Colorado 80026

Re: K233838

Trade/Device Name: Emprint Ablation System with Thermosphere Technology (Overall System Name); Emprint Ablation Generator (CAGEN1); Emprint Ablation Generator HP (CAGENHP); Emprint Ablation Pump (CAPUMP1); Covidien™ Ablation Footswitch (RFASW); Emprint Reinforced Percutaneous Antenna 15cm (CA15L2); Emprint Reinforced Percutaneous Antenna 20cm (CA20L2); Emprint Reinforced Percutaneous Antenna 30cm (CA30L2); Covidien™ Remote Temperature Probe (RTP20); Covidien™ Remote Temperature Probe, Bulk (RTP20B)

Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: NEY
Dated: March 4, 2024
Received: March 5, 2024

Dear Steve Pavlik:

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: 2024.03.28 10:57:25 -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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K233838

Device Name
Emprint Ablation System with Thermosphere Technology (Overall System Name)

CAGEN1, CAGENHP, CAPUMP1, RFASW, CA15L2, CA20L2, CA30L2, RTP20, RTP20B

Indications for Use *(Describe)*
The Emprint™ ablation system is intended for use in percutaneous, laparoscopic, and intraoperative coagulation (ablation) of soft tissue, including partial or complete ablation of non-resectable liver tumors.

The Emprint™ ablation system is not intended for use in cardiac procedures.

The Emprint™ ablation system overlapping technique is only intended for use in the liver.

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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9.0 510(k) Summary

9.1 Submitter

Medtronic Inc
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Contact: Steven Pavlik
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Date of Summary Preparation: February 26, 2024

9.2 Devices

Table 1-1: Devices:

Device Trade Name	EmprintTM Ablation System with ThermosphereTM Technology
Device Common Name	Microwave Ablation System
Classification Name	System, Ablation, Microwave and Accessories
Regulatory Class	II
Product Code	NEY

9.3 Predicate Devices

This Special 510(k) submission describes up to date surgical techniques in the instructions for use with the Emprint™ Ablation System with Thermosphere™ Technology.

Table 1-2: Predicate Devices

Device Name	Classification Name and Class	510(k) Clearance No
Emprint™ Ablation System with Thermosphere™ Technology	System, Ablation, Microwave and Accessories; Class II	K133821, K163105, and K200796

9.4 Device Description

Medtronic has modified the Emprint Ablation System IFUs with Expanded Physician Techniques. The Emprint™ Ablation System with Thermosphere™ Technology, Covidien's microwave ablation system, was released for commercial distribution in the United States in April 2014.

The Emprint™ Ablation System is a microwave-based ablation system intended to deliver energy through an antenna inserted into soft tissue for the purpose of coagulating (ablating) a defined volume of that tissue. The Emprint™ Ablation System utilizes a 2450 MHz 100W, or 150W generator to deliver power to a single microwave ablation antenna. The Emprint™ Ablation 100W Generator is composed of analog and digital circuits with no software or firmware. The Emprint™ Ablation 150W Generator utilizes software and firmware, however both generators' settings are controlled in the same fashion. Emprint™ Ablation Generators provide for user setting of ablation time (0-10 minutes) and ablation power (5 to 150W). With an optional temperature probe, the ablation generators can be set to monitor the temperature of a desired target and to automatically shut the generator off when the target reaches a pre-set temperature.

The Emprint™ Ablation System uses circulating room temperature normal saline to cool the non-radiating portion of the antenna shaft and to provide a more consistent ablation zone. The normal saline is pumped from an IV bag through the antenna shaft and back to the IV bag in a closed system. No saline is in contact with the patient.

The 510(k) Cleared Emprint™ Ablation System consists of the following components:

- Emprint™ Ablation Generator (2450 MHz)
- Emprint™ HP Ablation Generator (2450 MHz)
- Emprint™ Percutaneous Antenna (sterile, single use)
- Emprint™ Ablation Reusable Cable
- Emprint™ Ablation Pump

The system also includes the following optional equipment/accessories:

- Emprint™ Ablation Cart (with Isolation Transformer)
- Emprint™ HP Ablation Cart (with Isolation Transformer)
- Ablation Footswitch
- Remote Temperature Probe (sterile, single use)

The system must be used with a standard IV bag of sterile normal saline (not provided with the system).

9.5 Indications for use

The Emprint™ ablation system is intended for use in percutaneous, laparoscopic, and intraoperative coagulation (ablation) of soft tissue, including partial or complete ablation of non-resectable liver tumors.

The Emprint™ ablation system is not intended for use in cardiac procedures.

The Emprint™ ablation system overlapping technique is only intended for use in the liver.

9.6 Description of Changes

Published literature describing use of the Emprint ablation system demonstrates use of both "overlapping" and "ramp-up" techniques, and currently the Emprint ablation system instructions for use do not describe those techniques. This 510(k) seeks to update the Emprint Ablation System instructions for use to include the techniques observed in published literature and utilized in clinician practice.

New packaging labels have been produced for this update of the Emprint Ablation System, however, changes to packaging labels are driven by procedural review and were not updated due to the additional techniques, new data for standard ablation zone charts, and warning information.

9.7 Comparison of technological characteristics with the predicate device

For this Special 510(k), The Emprint Ablation System with Thermosphere Technology has no change in technological characteristics. There are no changes to the underlying technology. The fit, form, and function of the system remains unchanged.

9.8 Clinical Background

Creating ablation zones with multiple "overlapping" activations is a technique common to thermal ablation in the liver, either through simultaneous activation of multiple applicators or through sequential activation of a single repositioned applicator. The approach is used to achieve desired ablative margins around tumor sizes within NCCN Colon Cancer, NCCN Neuroendocrine Tumor and BCLC hepatocellular carcinoma guidelines (up to 5 cm). Similarly, a power "ramp-up" technique is common, wherein a single ablation zone is created without repositioning the device while gradually increasing the system power setting. Published literature describing use of the Emprint ablation system demonstrates use of both "overlapping" and "ramp-up" techniques and currently the Emprint ablation system instructions for use do not directly cover the techniques.

9.9 Performance Data

Characterization testing was conducted to generate the zone charts for the updated techniques being added to the Emprint Ablation System Percutaneous Antenna IFU.

9.9.1 Bench Testing

To provide guidance for the ablation techniques, additional bench testing was conducted in ex-vivo Bovine liver to collect the data which will populate the new zone chart tables relevant to the updated techniques in the IFUs, and 125W ablation zones. The bench testing results are

summarized in the Design Control Activities.

9.9.2 Clinical Testing

Clinical Studies in human subjects were not required to demonstrate the performance and safety of the Emprint Ablation System with Thermosphere Technology.

9.9.3 Animal Testing

Studies or testing in animal subjects were not required to demonstrate the performance and safety of the Emprint Ablation System with Thermosphere Technology.

9.10 Conclusion

The Emprint Ablation System with Thermosphere technology which includes the updated surgical techniques (subject device) and the previously cleared Emprint Ablation System with Thermosphere Technology (predicate device) have the same performance, safety, and effectiveness based on pre-clinical testing, and risk assessment. As a result, the subject Emprint Ablation System with Thermosphere Technology that includes updated surgical techniques does not raise any new questions of safety and effectiveness and is shown to be substantially equivalent to the predicate device.