February 13, 2020

Covidien LLC
Medtronic Inc.
Hilla Debby
Director Regulatory Affairs
6135 Gunbarrel Ave
Boulder, CO 80301

Re: K193232
Trade/Device Name: Emprint Ablation System with Thermosphere Technology, Emprint SX Ablation Platform with Thermosphere Technology
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: NEY
Dated: January 22, 2020
Received: January 23, 2020

Dear Hilla Debby:

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)*

K193232

Device Name

Emprint™ Ablation System with Thermosphere™ Technology
Emprint™ SX Ablation Platform with Thermosphere™ Technology

Indications for Use *(Describe)*

The Emprint™ Ablation System with Thermosphere™ Technology:

The Emprint™ Ablation System is intended for use in percutaneous, laparoscopic, endoscopic, and intraoperative coagulation (ablation) of soft tissue, including partial or complete ablation of nonresectable liver tumors.

The Emprint™ Ablation System is not intended for use in cardiac procedures.

The Emprint™ SX Ablation Platform with Thermosphere™ Technology:

The Emprint™ SX Ablation Platform with Thermosphere™ Technology is intended for use in percutaneous, laparoscopic, and intraoperative coagulation (ablation) of soft tissue, including partial or complete ablation of nonresectable liver tumors.

The Emprint™ SX Ablation Platform is not intended for use in cardiac procedures.

The system's optional, 3-D navigation feature assists in the placement of the Emprint™ SX Navigation Antenna with Thermosphere™ Technology using real-time image guidance during intraoperative and laparoscopic ablation procedures. The navigation feature enhances the output of a compatible medical ultrasound imaging system and displays an image of the antenna and its predicted trajectory on a computer monitor. The size and shape of the predicted ablation zone relative to the position of the antenna is displayed on the enhanced ultrasound image.

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

I. Submitter

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POB 258 Yoqneam, IL 20692
Date of Summary Preparation: November 22, 2019

II. Devices

Table 5.1 Devices:

Device Trade Names	Emprint™ Ablation System with Thermosphere™ Technology
	Emprint™ SX Ablation Platform with Thermosphere™ Technology
Device Common Name	Microwave Ablation System
Classification Name	System, Ablation, Microwave and Accessories
Regulatory Class	II
Product Code	NEY

III. Predicate devices

This Special 510(k) submission describes changes to the Instructions for Use (IFU) and modifications to the Antenna's previously cleared for the Emprint™ Ablation System with Thermosphere™ Technology and Emprint™ SX Ablation Platform with Thermosphere™ Technology. The modified Emprint™ Ablation System with Thermosphere™ Technology and the modified Emprint™ SX Ablation Platform with Thermosphere™ Technology are substantially equivalent to the predicate devices outlined in Table 5.2.

No reference devices were used in this submission

Table 5.2 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
Emprint™ Ablation System with Thermosphere™ Technology	System, Ablation, Microwave and Accessories; Class II	K163105
Emprint™ SX Ablation Platform with Thermosphere™ Technology	System, Ablation, Microwave and Accessories; Class II	K171358

IV. Device description

The Emprint™ Ablation System with Thermosphere™ Technology, Covidien's microwave ablation platform, was released for commercial distribution in the United States in April 2014.

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

1. Emprint™ Ablation Generator (2450 MHz)
2. Emprint™ Percutaneous Antenna (sterile, single use)
3. Emprint™ Ablation Reusable Cable
4. Emprint™ Ablation Pump

The system also includes the following optional equipment/accessories:

5. Emprint™ Ablation Cart
6. Ablation Footswitch
7. Isolation Transformer
8. Remote Temperature Probe (sterile, single use)

The ablation platform must be used with a standard IV bag of sterile, normal saline (not provided with the device).

In 2016 Covidien LLC made changes to improve the usability of the Emprint™ Ablation System's percutaneous antenna, by increasing the stiffness of the antenna's shaft. Like the predicate antenna approved via traditional 510(k) (K133821), the modified antenna is manufactured in 3 lengths (15, 20 and 30 cm) and is uniquely identified by catalog numbers (CA15L2, CA20L2 and CA30L2).

Covidien made the change to accommodate a usability-related preference, expressed by physicians. The modification was not in response to reported device malfunctions or adverse events associated with the current, more-flexible ablation antenna.

This change in stiffness enhances the antenna's usability; and has no effect on the system's essential function, performance or underlying principles of operation.

The Emprint™ SX Ablation Platform with Thermosphere™ Technology is a microwave ablation system with an optional navigation feature. It relies on the same principles of operation, fundamental technology, and performance characteristics as its predicate, the Emprint™ Ablation

System with Thermosphere™ Technology (K133821, K163105).

The main differences between the Emprint™ SX Ablation Platform with Thermosphere™ Technology and the predicate device include software (vs. manual) control of the generator and pump, as well as the addition of an optional navigation feature. Both systems include a 2.45 GHz microwave generator, a cooling pump, and accessories. A bag/bottle of sterile fluid that connects to the antenna's tubing and to the peristaltic pump is required for proper system operation. The 510(k) Cleared Emprint™ Percutaneous Antenna (K163105) can be used with either system to create predictable, spherical ablation zones in soft tissue in percutaneous, laparoscopic, and intraoperative procedures.

The Emprint™ antenna, the applied part of the Emprint™ ablation system with Thermosphere™ Technology and Emprint™ SX ablation platform with Thermosphere™ Technology that delivers microwave energy to the patient, has a sharp, engineered ceramic tip (called "trocar") at the distal end of the device that allows a user to puncture tissue. The shaft of the disposable antenna is inserted directly into the tissue intended to be ablated. The radiating tip of the antenna shaft delivers microwave energy to the target tissue.

Modifications have been made to the Emprint™ Ablation System and Emprint™ SX Ablation Platform's IFU's and Antenna's. Updates were made to the IFU to reduce the possible trocar detachment post ablation resulting from atypical use.

Changes made to the bond curing schedule is to enhance the bond strength between the trocar and the fiberglass shaft.

Additionally, the clear non-stick heat shrink was extended further on the antennae to reduce tissue adherence post ablation.

The Antenna changes mentioned above do not affect the Emprint™ Ablation System with Thermosphere™ Technology and Emprint™ SX Ablation Platform with Thermosphere™ Technology essential function, performance or underlying principles of operation.

Extensive bench verification testing was conducted to ensure the modified Emprint™ Percutaneous Antenna performs as designed and meets essential requirements. The device modification was implemented in compliance with FDA's quality system and design control requirements.

V. Description of Changes

A. INSTRUCTIONS FOR USE (IFU) UPDATE

The following language (see table 5.3 below) was added to the Instructions for Use (IFU) for both the Emprint™ Ablation System with Thermosphere™ Technology and Emprint™ SX Ablation Platform with Thermosphere™ Technology:

> "5. When energy delivery to the antenna stops, allow the pump to continue running for five seconds to cool the antenna. Then rotate the antenna shaft to release any adhered tissue. Then reposition or remove the antenna."

Additionally, several minor edits, unrelated to trocar detachment from atypical use, were included in the instructions for use.

Table 5.3 Language Change Summary for IFU:

Product Code	Description	Change Description	Name of the Devices	510 (k) Clearance No.
PT00101561 (English)	Instruction for Use (IFU)	• **Added** "When energy delivery to the antenna stops, allow the pump to continue running for five seconds to cool the antenna. Then rotate the antenna shaft to release any adhered tissue. Then reposition or remove the antenna." • **Additionally**, several clarifications were included in the instructions for use updates.	Emprint™ Ablation System with Thermosphere™ Technology	K133821 and K163105
PT00102817 (English)	Instruction for Use (IFU)	• **Added** "When energy delivery to the antenna stops, allow the pump to continue running for five seconds to cool the antenna. Then rotate the antenna shaft to release any adhered tissue. Then reposition or remove the antenna." • **Additionally**, several clarifications were included in the instructions for use updates.	Emprint™ SX Ablation Platform with Thermosphere™ Technology	K171358

B. BOND CURE SCHEDULE CHANGE

Changes have been made to the bond cure schedule in order to increase the bond strength between the trocar and the fiberglass shaft.

C. CLEAR NON-STICK HEAT SHRINK DESIGN CHANGE

The clear non-stick heat shrink was extended further on the antennae to reduce tissue adherence.

VI. Indications for use

Modifications made to the Antenna's do not alter the Indications for use (shown below) for the Emprint™ Ablation system and the Emprint™ SX ablation platform.

The Emprint™ Ablation System with Thermosphere™ Technology:

The Emprint™ Ablation System is intended for use in percutaneous, laparoscopic, endoscopic, and intraoperative coagulation (ablation) of soft tissue, including partial or complete ablation of nonresectable liver tumors.

The Emprint™ Ablation System is not intended for use in cardiac procedures.

The Emprint™ SX Ablation Platform with Thermosphere™ Technology:

The Emprint™ SX Ablation Platform with Thermosphere™ Technology is intended for use in percutaneous, laparoscopic, and intraoperative coagulation (ablation) of soft tissue, including partial or complete ablation of nonresectable liver tumors.

The Emprint™ SX Ablation Platform is not intended for use in cardiac procedures.

The system's optional, 3-D navigation feature assists in the placement of the Emprint™ SX Navigation Antenna with Thermosphere™ Technology using real-time image guidance during intraoperative and laparoscopic ablation procedures. The navigation feature enhances the output of a compatible medical ultrasound imaging system and displays an image of the antenna and its predicted trajectory on a computer monitor. The size and shape of the predicted ablation zone relative to the position of the antenna is displayed on the enhanced ultrasound image.

VII. Comparison of technological characteristics with the predicate device

The Emprint™ Ablation System with Thermosphere™ Technology and Emprint™ SX Ablation Platform with Thermosphere™ Technology current antennae (predicate device's) and the modified ablation antenna share the same underlying technology. Both devices are used to deliver microwave energy to soft tissue in a highly controlled way. Signal frequency, power and exposure time are controlled by the system's 2450 MHz generator. The design of the radiating portion of the accessory and continuous cooling of the accessory during the ablation procedure determines the shape (near spherical) and size of the resulting ablations.

The modification to the antennae trocar bonding and clear non-stick heat shrink extension have improved parameters such as tensile bond strength, antenna insertion force and antenna extraction force compared to the current device (predicate) without affecting the design requirements and the essential performance of the antenna and the system as a whole.

VIII. Performance data

Non-clinical performance data was provided in support of the substantial equivalence determination.

a) Bench Verification Testing

Verification testing was conducted to:(1) demonstrate the modified antenna's trocar bond strength was greater than the predicate, (2) confirm that the change did not impact the reliability of the device by performing thermal ablations in soft tissue during the extended use test. (3) quantify and compare the frictional force between the modified antenna and the adjustable depth guide, insertion force and extraction force (ex-vivo liver tissue) of the modified antenna relative to the 510(k) cleared devices.

IX. Conclusions

The modified Emprint™ Ablation System with Thermosphere™ Technology and Emprint™ SX Ablation Platform with Thermosphere™ Technology antennae are identical to the predicate device's, except for bond cure schedule change and clear non-stick heat shrink design change. The subject and predicate devices share the same intended use, technological characteristics, and meet identical performance requirements. The results of comprehensive verification testing raised no new questions of safety or effectiveness. The Emprint™ Ablation System with Thermosphere™ Technology and Emprint™ SX Ablation Platform with Thermosphere™ Technology Antennae (subject device) and the modified antennae are substantially equivalent.