December 17, 2020

Medtronic Inc.
Liron Bar-Yaakov
Senior Manager of Regulatory Affairs
5920 Longbow Dr.
Boulder, Colorado 80301

Re: K203303
Trade/Device Name: 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: November 4, 2020
Received: November 9, 2020

Dear Liron Bar-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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K203303

Device Name
The Emprint™ SX Ablation Platform with Thermosphere™ Technology

Indications for Use *(Describe)*
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 non-resectable liver tumors.

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

The system's optional 3D 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 zone relative to the position of the antenna are 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

Medtronic Inc
5920 Longbow Dr.
Boulder, CO 80301

Contact: Liron Bar-Yaakov
Senior Manager of Regulatory Affairs
5920 Longbow Dr
Boulder, CO 80301
Telephone: (508) 261-8000
Email: Liron.Baryaakov@medtronic.com

Date of Summary Preparation: November 05, 2020

II. Devices

Table 5.1 Devices:

Device Trade Name	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 enhancements to the software of the previously cleared Emprint™ SX Ablation Platform with Thermosphere™ Technology.

Table 5.2 Predicate Devices

Device Name	Classification Name and Class	510(k) Clearance No
Emprint™ SX Ablation Platform with Thermosphere™	System, Ablation, Microwave and Accessories; Class II	K171358

IV. Device Description

The Emprint™ SX Ablation Platform with Thermosphere™ Technology is microwave-based system intended to deliver energy through an antenna inserted into soft tissue for the purpose of coagulating (ablating) a defined tissue volume. The Emprint™ SX Ablation Platform utilizes a 2450 MHz 100W generator to deliver power to a single microwave ablation antenna. The platform is software-controlled and a touchscreen Graphical User Interface is used to select the desired ablation time (up to 10 minutes) and power (5 to 100W) settings. Using an optional temperature probe, the ablation platform can be set to monitor the temperature of a desired target and to automatically turn the generator off, when the target reaches a pre-set temperature. The ablation platform uses circulating, room-temperature, normal saline to cool the non-radiating portion of the antenna shaft and to provide a 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.

Using an optional/selectable navigation feature, the Emprint™ SX Ablation Platform assists physicians in the accurate placement of the trackable Emprint™ SX Navigation Antenna into a target anatomical structure by overlaying the image of the antenna and its trajectory onto an ultrasound image in real time.

Sensors are attached to platform-compatible, open and laparoscopic ultrasound probes and to the platform's trackable antenna. These sensors detect fluctuations in an electromagnetic field emitted from the system's Table Top Field Generator (TTFG). The TTFG is placed underneath the patient and transmits positional information that is processed by the system's navigation hardware and interpreted by its software. The platform's software allows the surgeon to see a representation of the ablation zone on an auxiliary display and the system's operator to control the ablation system via the touchscreen interface.

Table 5.3 Emprint™ SX Ablation Platform components:

Component Name	Catalog No.
Emprint™ SX Ablation Platform with Thermosphere™ Technology	CASYS100
Emprint™ SX Ultrasound Surgical Navigation (software) Application	CAUS1SN
Emprint™ Ablation Reusable Cable	CA190RC1
Emprint™ SX Table Top Field Generator	CAFG1
Emprint™ SX Table Top Field Generator Cart	CAFGCART1
Emprint™ SX Field Generator Spacers (Bed Pads)	CAFGSP1
Emprint™ SX Short Navigation Antenna with Thermosphere™ Technology, 15cm	CA15L2N
Emprint™ SX Standard Navigation Antenna with Thermosphere™ Technology, 20cm	CA20L2N
Emprint™ SX Long Navigation Antenna with Thermosphere™ Technology, 30cm	CA30L3N
Emprint™ SX Open Ultrasound Tracking Sensor	CABK8816
Emprint™ SX Open Ultrasound Tracking Sensor	CAAL9132
Emprint™ SX Laparoscopic Ultrasound Tracking Sensor	CAAL9150L
Emprint™ SX Laparoscopic Ultrasound Tracking Sensor	CABK8666L
Remote Temperature Probe	RTP20
Ablation Footswitch	RFASW

V. Description of Changes

Modifications have been made only to the software of the Emprint™ SX Ablation Platform with Thermosphere™ Technology. Enhancements were made to the Software to allow the user to clear a general system error without power-cycling the system in order to deliver ablation therapy, mitigating any risk of delay in procedure.

These software changes, do not affect the Emprint™ SX Ablation Platform with Thermosphere™ Technology indication for use, essential function, performance, or underlying principles of operation.

VI. Indications for use

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

Emprint™ SX Ablation Platform with Thermosphere™ Technology current software (predicate device) and the updated software update 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 enhancement to CAUS1SN software allows the user to avoid power cycling the system removing a delay to the procedure due to the receipt of a general system error. This is completed through a feature update to the Emprint API code, responsible for processing messages from the generator. There are no effects on any other portion of the software architecture, or on the systems underlying technological characteristics.

VIII. Performance Data

Comprehensive SW Verification testing was performed by Medtronic in support of the proposed change. No additional pre-clinical or clinical data is required to support the substantial equivalence determination for this software update.

IX. Conclusions

The Modified Emprint™ SX Ablation Platform with Thermosphere™ Technology software (CAUS1SN) update is nearly identical to the predicate Emprint™ SX Ablation Platform with Thermosphere™ Technology software. 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 current Emprint™ SX Ablation Platform with Thermosphere™ Technology software version, and the Emprint™ SX Ablation Platform with Thermosphere™ Technology new software version are substantially equivalent.