August 26, 2020

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

Re: K200796
Trade/Device Name: Emprint Ablation System 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: March 25, 2020
Received: July 20, 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)*
K200796

Device Name
Emprint™ Ablation System with Thermosphere™ Technology

Indications for Use *(Describe)*

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

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

Type of Use *(Select one or both, as applicable)*

[x] Prescription Use (Part 21 CFR 801 Subpart D) [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) Summary

I. Submitter

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Date of Summary Preparation: 25 March 2020

II. Devices

Table 5.1 Devices

Device Trade Names	Emprint™ Ablation System with Thermosphere™ Technology
Device Common Name	Microwave Ablation System
Classification Name	System, Ablation, Microwave and Accessories
Regulation Number	21 CFR 878.4400
Regulatory Class	II
Product Code	NEY

III. Predicate devices

This Traditional 510(k) submission describes the addition of a new system component (Emprint™ HP Ablation Generator - CAGENHP) and its optional accessory (Emprint™ HP Ablation Cart - CARTHP) as well as new and updated IFU's for the Emprint™ Ablation System with Thermosphere™ Technology.

The Emprint™ Ablation System with the addition of the Emprint™ HP Generator - CAGENHP and its optional accessory (Emprint™ HP Ablation Cart - CARTHP) is substantially equivalent to the predicate devices outlined in Table 5.2.

Table 5.2 Predicate Device

Device Trade Names	Emprint™ Ablation System with Thermosphere™ Technology
Device Common Name	Microwave Ablation System
Classification Name	System, Ablation, Microwave and Accessories
Regulation Number	21 CFR 878.4400
Regulatory Class	II
Product Code	NEY
510(k) Clearance No.	K193232

Table 5.3 Reference Device

Device Trade Names	Emprint™ Ablation System with Thermosphere™ Technology
Device Common Name	Microwave Ablation System
Classification Name	System, Ablation, Microwave and Accessories
Regulation Number	21 CFR 878.4400
Regulatory Class	II
Product Code	NEY
510(k) Clearance No.	K133821

IV. Device description

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 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 (with Isolation Transformer)
6. Ablation Footswitch
7. Remote Temperature Probe (sterile, single use)

The current Emprint™ Ablation System utilizes a 2450 MHz 100W generator (CAGEN1) to deliver power to a dedicated single microwave ablation antenna. The optional cart, Emprint™ Ablation Cart is intended to be used with the Emprint™ Ablation Generator.

The new system component, Emprint™ HP Ablation Generator (CAGENHP) [subject device] is similar to the device, Emprint™ Ablation Generator (CAGEN1) [predicate device] as described in K193232 with two exceptions. The new system component, Emprint™ HP Ablation Generator (CAGENHP), will extend the power setting range from 5 to 100W (Emprint™ Ablation Generator - CAGEN1) to 5 to 150W. The increased power will allow clinicians to create larger ablation zones when ablating soft tissue lesions, compared to use of the system with the existing 100-watt microwave generator (CAGEN1). Further the Emprint™ HP Ablation Generator (CAGENHP) is composed of analog and digital circuits with software and firmware whereas the predicate Emprint™ Ablation Generator (CAGEN1), is composed of analog and digital circuits with no software or firmware. The Emprint™ HP Generator will be compatible with all current Emprint™ ablation system components and accessories except the cart. The new optional Emprint™ HP Cart (CARTHP) has been added to the system and is compatible with the Emprint™ HP Ablation Generator (CAGENHP).

The optional cart holds the Emprint™ HP Generator (CAGENHP) and the Emprint™ Ablation Pump (CAPUMP1) securely in one location. The optional footswitch can be placed on the cart's lower shelf. There are hooks on both sides of the cart which are meant to hold either the normal saline bag during a procedure, or to loop (and store) the reusable cable over while not in use.

Emprint™ HP Ablation Cart (CARTHP) is similar to the previously cleared (K193232) Emprint™ Ablation Cart (CART1), which holds the Emprint™ Generator (CAGEN1) and the Emprint™ Ablation Pump (CAPUMP1) securely in one location.

V. Indications for use

The addition of a new system component (Emprint™ HP Ablation Generator - CAGENHP) and its optional accessory (Emprint™ HP Ablation Cart - CARTHP) do not alter the Indications for use, shown below, for the Emprint™ Ablation system.

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.

VI. Comparison of technological characteristics with the predicate device

The addition of a new system component (Emprint™ HP Ablation Generator - CAGENHP) and its optional accessory (Emprint™ HP Ablation Cart - CARTHP) to the Emprint™ Ablation System with Thermosphere™ Technology does not alter the principles of operation and fundamental technology.

The Emprint™ Ablation System's performance with addition of a new system component (Emprint™ HP Ablation Generator - CAGENHP) and its optional accessory (Emprint™ HP Ablation Cart - CARTHP) is equivalent to its predicate device with respect to its intended use of soft tissue ablation in open, laparoscopic, endoscopic and percutaneous procedures.

The Emprint™ HP Ablation Generator (CAGENHP) and its optional accessory Emprint™ HP Ablation Cart (CARTHP) share the same underlying technology as the predicate devices,

Emprint™ Ablation Generator (CAGEN1) and its optional accessory Emprint™ Ablation Cart (CART1). Both CAGENHP and CAGEN1 are used to deliver microwave energy to soft tissue in a highly controlled way.

The new system component, Emprint™ HP Ablation Generator (CAGENHP) is used to coagulate (ablate) soft tissue in the same way, as the predicate Emprint™ Ablation generator. Although the Emprint™ HP Ablation Generator differs from the predicate device with respect to being able to deliver an extended power setting range from 5 to 100W to 5 to 150W and being software controlled when compared to the predicate device, performance data demonstrate that these differences do not impact the safety and effectiveness of the device.

The verification and validation activities conducted has shown that the addition of the optional accessory, Emprint™ HP Ablation Cart - CARTHP, has no impact on the safety and effectiveness of the Emprint™ Ablation System.

The addition of a new system component (Emprint™ HP Ablation Generator - CAGENHP) and its optional accessory (Emprint™ HP Ablation Cart - CARTHP) do not affect the design requirements and the essential performance of the system as a whole.

VII. Performance data

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

a) Bench Verification Testing

Bench testing was conducted at the system and subsystem level to demonstrate the following:

1. Emprint™ Ablation System with Emprint™ HP Ablation Generator and Emprint™ HP Ablation Cart (CARTHP) meets all design requirements.
2. Emprint™ Ablation System with Emprint™ HP Ablation Generator meets all ablation performance design requirements and to demonstrate that the ablations zone dimensions created with the Emprint™ HP Ablation Generator (subject) and Emprint™ Ablation Generator (predicate) are equivalent for identical power settings.
3. Verify that the previously approved Emprint™ Ablation System accessories (except the Emprint™ Ablation Cart – CART1) are compatible with the new Emprint™ HP Ablation Generator. Note: The new optional Emprint™ HP Ablation Cart (CARTHP) has been added to the system and is compatible with the Emprint™ HP Ablation Generator (CAGENHP).
4. The Emprint™ Ablation System with Emprint™ HP Ablation Generator meets IEC 60601-1-2:2014 EMC regulatory requirements.
5. Emprint™ Ablation System with Emprint™ HP Ablation Generator meets IEC 60601-1:2005 and IEC 60601-2-6:2016 safety requirements.
6. Verify the Emprint™ Ablation System with Emprint™ HP Ablation Generator (CAGENHP) and Emprint™ HP Ablation Cart (CARTHP) performs as specified within specified storage and use conditions.

7. Verify the usability of Emprint™ HP Ablation Generator (CAGENHP) to the Emprint™ Ablation System.
8. Verify the Emprint™ HP Ablation Generator (CAGENHP) and Emprint™ HP Ablation Cart (CARTHP) packaging can protect the generator and cart respectively during simulated transportation.

b) Animal Testing

The Emprint™ Ablation System with CAGENHP generator demonstrated equivalent performance in terms of ablation zone creation relative to the predicate control device (Emprint™ Ablation System with CAGEN1 generator) using the Emprint™ Percutaneous Antenna in an in vivo porcine model undergoing soft tissue ablation procedures. This GLP-compliant pivotal study verified the performance and procedural safety of the Emprint™ Ablation System with CAGENHP generator in an in vivo porcine model undergoing soft tissue ablation procedures.

c) Clinical Testing

Clinical studies in human subjects were not required to demonstrate the performance and safety of the new system component Emprint™ HP Ablation Generator (CAGENHP) and optional accessory Emprint™ HP Ablation Cart (CARTHP).

VIII. Biocompatibility

The biocompatibility of the Emprint™ Ablation System with Thermosphere™ Technology is not affected by the proposed addition of the new system component, The Emprint™ HP Ablation Generator (CAGENHP) and the optional accessory, and Emprint™ HP Ablation Cart (CARTHP).

The Emprint™ HP Ablation Generator (CAGENHP), and Emprint™ HP Ablation Cart (CARTHP) do not contact the patient, are reusable, not provided sterile and are not used in the sterile field. Cleaning instructions for these components are provided in the applicable user guides.

IX. Sterilization and Shelf Life

The sterilization and shelf life of the Emprint™ Ablation System with Thermosphere™ Technology is not affected by the proposed addition of the new system component, The Emprint™ HP Ablation Generator (CAGENHP) and the optional accessory, Emprint™ HP Ablation Cart (CARTHP). The Emprint™ HP Ablation Generator (CAGENHP) and Emprint™ HP Ablation Cart (CARTHP) are reusable, not provided sterile and are not used in the sterile field. Wipe down instructions for these components are provided in the applicable user guides.

X. Conclusions

The new system component, Emprint™ HP Ablation Generator (CAGENHP) is used to coagulate (ablate) soft tissue in the same way as the predicate Emprint™ Ablation Generator. Although the Emprint™ HP Ablation Generator differs from the predicate device with respect to being able to deliver an extended power setting range from 5 to 100W to 5 to 150W and being software controlled when compared to the predicate device, performance data demonstrate that these differences do not impact the safety and effectiveness of the device.

The verification and validation activities conducted have shown that the addition of the optional accessory, Emprint™ HP Ablation Cart, has no impact on the safety and effectiveness of the Emprint™ Ablation System.

Based on the information provided the Emprint™ HP Ablation Generator - CAGENHP (subject) is substantially equivalent to the Emprint™ Ablation Generator - CAGEN1 (predicate) and the optional accessory Emprint™ HP Ablation Cart - CARTHP (subject) is substantially equivalent to the optional accessory Emprint™ Ablation Cart – CART1 (predicate).