DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 6, 2016

Covidien LLC
Ms. Patti Arndt
Principal Regulatory Affairs Specialist
5920 Longbow Drive
Boulder, Colorado 80301

Re: K163105
Trade/Device Name: Emprint Ablation System
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, 2016
Received: November 7, 2016

Dear Ms. Arndt:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Jennifer R. Stevenson -A

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163105

Device Name

Emprint™ Ablation System

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 of non-resectable liver tumors.

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

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

Covidien llc
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Boulder, CO 80301

Contact Person: Patti Arndt
Principal Regulatory Affairs Specialist
Phone: 303-581-6668
FAX: 303-530-6313

Date of Summary Preparation: November 2, 2016

II. DEVICE

Device Trade Name:	Emprint™ Ablation System
Device Common Name:	Microwave Ablation System
Classification Name:	System, Ablation, Microwave and Accessories
Regulatory Class:	II
Product Code:	NEY

III. PREDICATE DEVICE

Emprint™ Ablation System with Thermosphere™ Technology, K133821

> Modification to System Accessory: Emprint™ Percutaneous Antenna with Thermosphere™ Technology: Catalog Nos.CA15L1 (Short), CA20L1 (Standard), CA30L1 (Long)

The device modification is not the subject of a design-related recall.

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

Covidien has modified the Emprint Ablation System's Percutaneous Antenna (Catalog Numbers: CA15L1, CA20L1 and CA30L1). The modified ablation antenna is identical to the device described in K133821, with two exceptions. The antenna's tissue contacting cooling jacket is manufactured from a new, biocompatible material that significantly increases the antenna's stiffness. Additionally, an adhesive has been added at the antenna shaft's proximal joint to strengthen the seal. By making the antenna stiffer, the cooling jacket material change is expected to enhance the antenna's usability; it does not affect the Emprint Ablation System's essential function, performance or underlying principles of operation.

Like its predicate, the modified antenna (Catalog Numbers CA15L2, CA20L2 CA30L2) is provided sterile (EO) and is intended for use with the Emprint Ablation System in health care facilities.

V. 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.

Indications for the use of the Emprint System and modified Percutaneous Antenna are identical to the predicate device.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Emprint Ablation System's current percutaneous antenna (predicate device) 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 antenna's cooling jacket (the component that forms the antenna's outer structure) changes the stiffness of the antenna's shaft only.

VII. PERFORMANCE DATA

The following non-clinical performance data were provided in support of the substantial equivalence determination.

Bench Verification Testing

Verification testing was conducted to (1) demonstrate the modified antenna's continued robustness to mechanical stresses, (2) confirm that the antenna's printed depth markings were not affected by the underlying cooling jacket material change, (3) quantify the stiffness of the antenna's shaft relative to the 510(k) cleared device and, (4) confirm that the change did not impact the system's essential function – the performance of thermal ablations in soft tissue. Some of the verification tests were conducted using the fully-assembled Emprint Percutaneous Antenna, while other tests required only the cooling jacket sub-assembly.

Product Stability Testing

Stability testing was conducted to evaluate the effect of the cooling-jacket material change on the antenna's performance over time. The testing was broad in scope and included mechanical stress testing, cytotoxicity testing and performance testing.

Biocompatibility Testing

Biocompatibility testing of the new fiberglass material and the modified cooling jacket subassembly was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing within a Risk Management Process. Additionally, the modified cooling jacket subassembly underwent a full chemical characterization.

Validation Testing

Representative end users participated in a simulated-use validation study. The participants completed a series of tasks designed to be representative of those performed with the antenna during ablation procedures. Objective and subjective test results confirmed that (1) essential and safety-critical tasks were performed with the stiffer antenna in a safe and effective manner, (2) the modified device met usability requirements and, (3) there were no new, use-related risks, associated with the change.

VIII. CONCLUSIONS

The modified Emprint Percutaneous Antenna is identical to the predicate device, with the exception of an improved seal and a material change that serves to increase the antenna's stiffness. The subject and predicate devices share the same intended use, technological characteristics, and meet identical performance requirements. The results of comprehensive verification and validation testing raised no new questions of safety or effectiveness and confirmed the usability enhancement. The Emprint Ablation System's Percutaneous Antenna (subject device) and the modified Percutaneous Ablation Antenna (predicate device) are substantially equivalent.