December 2, 2019

Covidien LLC
% Tim Thomas, RAC
VP Regulatory Affairs
Medtronic
6135 Gunbarrel Avenue
BOULDER CO 80301

Re: K192038
Trade/Device Name: Emprint™ Visualization Application
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: November 6, 2019
Received: November 7, 2019

Dear Mr. Thomas:

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,

Thalia T Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
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)*

K192038

Device Name

Emprint™ Visualization Application

Indications for Use *(Describe)*

The Emprint™ Visualization Application is a stand-alone software product that allows physicians to visualize and compare CT and MRI imaging data. The display, annotation, and volume rendering of medical images aids in ablation procedures conducted using Emprint™ ablation systems. The software is not intended for diagnosis.

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 – K192038

510(k) Submitter/Holder

Covidien llc
15 Hampshire Street
Mansfield, MA 02048

Contact

Tim Thomas RAC

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Date of Summary Preparation

September 27, 2019

Name of Device

Device Trade Name:	Emprint™ Visualization Application
Device Common Name:	DICOM Viewer
Classification Name:	Picture Archiving and Communications System / Class II
Regulation:	21 CFR 892.2050
Regulatory Class:	II
Product Code:	LLZ
Special Controls:	Compliance with Voluntary Standards: (1) Digital Imaging and Communications in Medicine (DICOM) Standard (2) Joint Photographic Experts Group (JPEG) Standard, Society of Motion Picture and Television Engineers; (SMPTE) Test Pattern Note: The JPEG Standard does not apply, as the subject device does not include motion imaging.

Predicate Device

The Emprint™ Visualization Application is substantially equivalent to the following, commercially available predicate device:

Device Trade Name:	Emprint™ Ablation Visualization Application
Device Common Name:	DICOM Viewer
510(k) Numbers:	K180192
Manufacturer:	Covidien llc

Device Description

The Emprint™ Visualization Application is a software product that achieves its medical purpose without being part of the hardware of a medical device (SaMD).

The Emprint™ Visualization Application is used to support Emprint™-system ablation procedures by displaying patient CT and MRI images with modeled ablation zones / volumes. The application is a Windows™ desktop program that is installed on a hospital computer with local storage and a network connection. The software receives CT and MRI images by supporting DICOM connections with CT/MRI scanners and hospital PACS. The software's DICOM image viewer does not in any way alter the medical images. The device is designed to meet the procedure planning and evaluation needs of physicians conducting soft tissue ablation procedures using Emprint™-branded systems only.

Using the visualization application, clinicians can perform the following activities:

- Import standard DICOM images and view them in 3-dimensions
- Select and view specific anatomical features (e.g., soft-tissue lesions, anatomical landmarks)
- Measure and mark critical anatomical features / areas of interest
- Overlay and position virtual images of the Emprint™ ablation antenna and the anticipated thermal ablation zone onto the medical image
- Add textual annotations to images
- Export annotated plans for the patient's medical record or for use in a radiology or operating suite
- View and compare any 2 of the imported images, simultaneously.

Using these features, the physician can prepare for an Emprint™-system ablation procedure by viewing and annotating patient-specific anatomy. Additionally, images taken before, during, or after an ablation procedure can be compared for a specific patient, and images can be compared across patients.

Indications for Use

The Emprint™ Visualization Application is a stand-alone software product that allows physicians to visualize and compare CT and MRI imaging data. The display, annotation, and volume rendering of medical images aids in ablation procedures conducted using Emprint™ ablation systems.

The software is not intended for diagnosis.

Technological Characteristics

The visualization application is a DICOM (Digital Imaging and Communications in Medicine) image viewer. It relies on the same principle of operation and fundamental technology and has the same performance characteristics as the predicate device / previous version of software.

Performance Testing

Extensive software verification testing was conducted for the SaMD product and included both software subsystem and system-level verification. Subsystem testing included unit and integration testing, while system-level verification was conducted to fully evaluate the performance of the application's user interface. Additionally, system-level testing was conducted to verify the application's measurement accuracy (+/- 2 voxels).

During the product's development, Covidien followed a human-factors engineering (HFE) process and conducted simulated-use, validation testing to confirm that the visualization application met user needs and expectations.

Performance testing demonstrated the Emprint™ Visualization Application's compliance with the following international standards.

	International Standard
1	IEC 62304:2006, Medical Device Software – Software Life Cycle Processes
2	NEMA PS 3.1-3.20:2016, Digital Imaging and Communications in Medicine (DICOM)

Animal and Clinical Testing

The performance and safety of the Emprint™ Ablation Visualization Application was characterized using laboratory (bench) verification and simulated-use validation testing. Animal studies and clinical studies in human subjects were not required.

Comparison to Predicate Device

Key differences between the subject and predicate devices include the following:

- The subject device was designed using a new, more efficient architecture.

- Workflow/procedural steps were optimized/organized for ease of use and to remove redundancy from the application. The predicate device (Emprint™ Ablation Visualization Application, Version 1.4), provides the user with the same functionality as the subject device, but requires the physician to use four different workflows. A separate workflow is required for each tissue type (liver ablation, kidney ablation, and lung ablation) and, also, for the application's 'Compare Images" feature. In the subject device (Emprint™ Ablation Application, Version 2.0), a single workflow is used for all tissue types and to implement the "Compare Images" feature. In addition to improving the software's usability, this change significantly reduces the amount of disk storage space required by the application.

- The user interface was optimized to reflect the application's use in the CT suite, where images are acquired during the procedure to confirm the antenna's position and trajectory, immediately prior to ablation. The application's workflow reflects its intraprocedural use and better supports clinical decisions for ablations performed in the CT suite.

- The subject device may be used with both MRI and CT images, as opposed to CT images only (predicate device).

The Emprint™ Visualization Application relies on the same principles of operation and fundamental technology and has essentially the same performance characteristics and intended use as its predicate. The subject device uses the same operating mechanism as the predicate device to size and display predicted ablation zones onto an image series. Like the predicate device, the Emprint™ Visualization Application references zone charts (look-up tables) that characterize the performance of the 510(k)-cleared Emprint™ Ablation System (K133821) and Emprint™ SX Ablation Platform (K171358).

Conclusion

The Emprint™ Visualization Application is used to plan and evaluate soft-tissue ablation procedures conducted with Emprint™-branded ablation systems in the same way as the predicate device / previous software version. The subject and predicate devices are both DICOM image viewers and comply with the associated NEMA DICOM Standard. Differences between the subject and predicate devices include architecture design and usability enhancements – none of which impact the SaMD product's intended use, measurement accuracy, underlying technology, principle of operation, or raise new questions of safety and effectiveness. The Emprint™ Visualization Application (subject device) and Emprint™ Ablation Visualization Application (predicate device) are substantially equivalent.