Covidien LLC
% Ms. Patti Arndt
Principal Regulatory Affairs Specialist
5920 Longbow Drive
BOULDER CO 80301

March 21, 2018

Re: K180192
Trade/Device Name: Emprint™ Ablation Visualization Application
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: January 23, 2018
Received: January 25, 2018

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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)*

K180192

Device Name

Emprint™ Ablation Visualization Application

Indications for Use *(Describe)*

The Emprint™ Ablation Visualization Application is a stand-alone software product that allows physicians to visualize and compare CT 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary – K180192

510(k) Submitter/Holder

Covidien llc
15 Hampshire Street
Mansfield, MA 02048

Contact

Patti Arndt
Principal Regulatory Affairs Specialist
Phone: 303-581-6668
Fax: 303-530-6313
Email: patti.l.arndt@medtronic.com

Date of Summary Preparation

March 19, 2018

Name of Device

Device Trade Name:	Emprint™ Ablation 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™ Ablation Visualization Application described in this submission is substantially equivalent to the following, commercially available predicate device:

Device Trade Name:	Emprint™ Procedure Planning Application
Device Common Name:	DICOM Viewer
510(k) Numbers:	K142048
Manufacturer:	Covidien llc

Device Description

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

The visualization application is a DICOM image viewer that allows surgeons and interventionists to utilize a health care facility's PACS (Picture Archiving and Communications System) server (or other digital media transfer process) to view and interact with CT images. Using pre-procedure, intra-procedure and post-procedure CT images, physicians can both plan and evaluate soft-tissue ablation procedures conducted with the Emprint™ Ablation System (K133821) and the Emprint™ SX Ablation Platform (K171358). The application is designed to streamline and enhance the procedure planning, execution and evaluation process; it is not required for the safe and effective conduct of an Emprint™ ablation procedure.

Using the application's three ablation workflows (Liver, Lung and Kidney Ablation), physicians can prepare for or evaluate an Emprint™ system ablation procedure by viewing and annotating patient-specific anatomy. The visualization application's Compare Workflow facilitates the comparison of images across patients, or the comparison of images from the same patient before and after an ablation procedure. Physicians can use the software to perform the following, key, workflow-based tasks:

- Import standard DICOM images and render 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
- Save annotated plans for future viewing
- 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 DICOM datasets, simultaneously

The visualization application is designed for installation and use on Windows™-based computers (Windows™ 7 or 10) and is compatible with procedure plans that were generated with the predicate device (Emprint™ Procedure Planning Application, K142048).

Indications for Use

The Emprint™ Ablation Visualization Application is a stand-alone software product that allows physicians to visualize and compare CT 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.

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 user interface for the visualization application's workflows. 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™ Ablation 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 3.1-3.20:2014, 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 and Similarities

There are two principal differences between the subject and predicate device. First, the Emprint™ Procedure Planning Application (K142048) was provided to users on a dedicated lap-top computer, while the Emprint™ Visualization Application is a stand-alone software product. This decoupling of the procedure planning software from a dedicated hardware platform allows users to install and use the software on a compatible computer of their choice. Secondly, the new software product does not include a VATs workflow that was designed for use by thoracic surgeons for the planning of non-ablation, surgical procedures. The subject device is configured to meet the procedure planning and evaluation needs of physicians conducting soft tissue ablation procedures using Emprint™-branded systems only.

The Emprint™ Ablation Visualization 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 Emprint™ Procedure Planning Application (K142048) to size and display predicted ablation zones in the software's Liver and Lung Ablation Workflows, as well as in the new Kidney Ablation Workflow. Like the predicate device, the Emprint Ablation Visualization Application does not calculate predicted ablation zones automatically, but references zone charts (look-up tables) that characterize the performance of the 510(k)-cleared Emprint Ablation System (K133821).

Conclusion

The Emprint™ Ablation 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 Emprint™ Procedure Planning Application. 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 minor configuration changes 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™ Ablation Visualization Application (subject device) and Emprint™ Procedure Planning Application (predicate device) are substantially equivalent.