December 16, 2019

AtriCure, Inc.
Caitlin Wunderlin
Regulatory Affairs Specialist
7555 Innovation Way
Mason, Ohio 45040

Re: K193162
Trade/Device Name: EPi-Sense Guided Coagulation System with VisiTrax
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: OCL
Dated: November 14, 2019
Received: November 15, 2019

Dear Caitlin Wunderlin:

This letter corrects our substantially equivalent letter sent on December 13, 2019.

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 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,

Nicole M. Gillette -S

Nicole Gillette
Acting Assistant Director
Division of Cardiac Electrophysiology, Diagnostics and Monitoring Devices
Office of Cardiovascular 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)*
K193162

Device Name
EPi-Sense Guided Coagulation System with VisiTrax

Indications for Use *(Describe)*
The EPi-Sense Guided Coagulation System with VisiTrax is intended for the coagulation of cardiac tissue using Radiofrequency (RF) energy using thoracoscopic, endoscopic, and laparoscopic surgical techniques.

The EPi-Sense Guided Coagulation System with VisiTrax may be used for temporary cardiac signal sensing and recording during surgery when connected to an external recording device.

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.

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"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

I. Applicant Information

Manufacturer: AtriCure®, Inc.
7555 Innovation Way
Mason, Ohio 45040
P: 513-755-4100

Contact Person: Caitlin Wunderlin
Regulatory Affairs Specialist

Alternate Contact: Jonathan McElwee
Sr. Manager, Regulatory Affairs

Date Prepared: 14 November 2019

II. Device Information

Proprietary Name: EPi-Sense Guided Coagulation System with VisiTrax®

Common Name: Guided Coagulation System

Classification: Surgical device for cutting, coagulation, and/or ablation of tissue, including cardiac tissue
Regulatory Class: Class II; per 21 CFR 878.4400
Product Code: OCL
Classification Panel: Cardiovascular

Predicate Device: EPi-Sense Guided Coagulation System with VisiTrax (K142084, 28 October 2014)

III. Device Description

The EPi-Sense Guided Coagulation System flexible, cooled electrode device, with a suction stabilizer feature, transmits radiofrequency (RF) energy from an Electrosurgical RF Generator (non-sterile, re-useable) connected through an Instrument Cable (sterile). The device is designed to produce local tissue heating which results in coagulation of cardiac tissue. A temporary sensing electrode feature may be used with an off-the-shelf electrogram recording system with the use of an additional instrument cable (non-sterile).

The Subtle Cannula is a sterile, single-use access tool used to introduce the EPi-Sense probe into the chest cavity. The cannula is a 30 cm or 40 cm long device with a large central lumen to accommodate both the EPi-Sense probe and a commercially available laparoscope for visualization. The cannula is comprised of a distal tip, a shaft with a textured grip at the proximal end, a vacuum line and an integrated guidewire.

The Sensing Cable is a reusable, non-sterile cable that provides connection for the sensing electrodes of the EPi-Sense probe to a commercially available external electrogram recording system.

The Subtle Cannula and Sensing Cable are accessories to the EPi-Sense Guided Coagulation System.

IV. Indications for Use

The EPi-Sense Guided Coagulation System with VisiTrax is intended for the coagulation of cardiac tissue using Radiofrequency (RF) energy using thoracoscopic, endoscopic, and laparoscopic surgical techniques.
The EPi-Sense Guided Coagulation System with VisiTrax may be used for temporary cardiac signal sensing and recording during surgery when connected to an external recording device.

V. A. Device Changes From Predicate

The changes for the CSK-2030 Sensing Cable include:

- Overmolded strain reliefs
- Overmolded yoke
- In-line receptacle
- In-line receptacle strain relief

The changes for the Subtle Cannula include:

- Shortened shaft and internal spring
- Lengthened molded tip
- Added lumens and NiTi wires
- Shortened stainless steel wires

B. Comparison of Technological Characteristics

- The devices include the same intended use, and;
- No changes were made in operating principle, or specifications of performance, and;
- The biocompatibility remains unchanged, and;
- The results of the verification and validation testing:
    - Demonstrated equivalency in mechanical performance and system compatibility
    - Compliance to IEC 60601-2-2 was met
    - Did not raise any new issues of safety or effectiveness

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VI. Performance Data

Mechanical design verification testing was completed per AtriCure's Quality System to verify the device's conformance to appropriate design controls and specifications to demonstrate equivalence to the previously cleared Sensing Cable and Subtle Cannula devices. The modified devices met the new and existing predetermined acceptance criteria ensuring substantial equivalence to the previously cleared K142084 cannula device. No new safety or performance issues were raising during testing.

VII. Conclusions

AtriCure demonstrated that the EPi-Sense Guided Coagulation System with modified Sensing Cable and Subtle Cannula is substantially equivalent in fundamental design, technology, function, device materials, packaging, sterilization, operating principle, and intended use/ indication for use as the previously cleared EPi-Sense Guided Coagulation System via K142084 on 28 October 2014.