July 24, 2019

AtriCure, Inc
Jake Lawson
Associate Regulatory Affairs Specialist
7555 Innovation Way
Mason, Ohio 45040

Re: K190587
Trade/Device Name: Coolrail Linear Pen (MCR1)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: OCL
Dated: March 6, 2019
Received: March 7, 2019

Dear Jake Lawson:

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,

Mark Fellman
Assistant Director
DHT2A: Division of Cardiac Electrophysiology,
Diagnostics and Monitoring Devices
OHT2: 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)*
K190587

Device Name
Coolrail Linear Pen (MCR1)

Indications for Use *(Describe)*
The Coolrail linear pen is a sterile, single use electrosurgery device intended to ablate cardiac tissue during cardiac surgery using radiofrequency (RF) energy.

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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510(k) Summary

I. Applicant Information

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

Contact Person: Jake Lawson
Associate Regulatory Affairs Specialist

Alternate Contact: Jim Taufen
Principal Regulatory Affairs Specialist

Date Prepared: 03 April 2019

II. Device Information

Proprietary Name: Coolrail® Linear Pen (MCR1)

Common Name: Electrosurgical device

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: Coolrail Linear Pen (MCR1)
(K183065, 4 December 2018)

III. Device Description

The AtriCure Coolrail Linear Pen (MCR1) is a hand held, single use surgical instrument intended for the ablation of cardiac tissues during cardiac surgery. The pen utilizes bipolar energy generated by the AtriCure Ablation and Sensing Unit (ASU) and is used with the AtriCure Switch Matrix (ASB3), a passive source switch, and footswitch. The Coolrail linear pen is designed with internally cooled electrodes to reduce thermal heating allowing for the energy to traverse deeper and more consistently into the target tissue. The ASU delivers bipolar radiofrequency (RF) energy, which flows between the internally cooled electrodes of the Coolrail linear pen. The Operator controls the application of energy by pressing the footswitch.

IV. Intended Use/ Indications for Use

The Coolrail® linear pen is a sterile, single use electrosurgery device intended to ablate cardiac tissue during cardiac surgery using radiofrequency (RF) energy.

V. Comparison of Technological Characteristics

- The proposed device has modified circuitry (within the RF and Pump control module) to add an additional thermistor safeguard, and;
- The devices include the same intended use, and;
- No changes were made in operating principle, or specifications of performance, and;
- The contraindications, warnings, and precautions remain the same for both the proposed and predicate, and;
- The devices are applied to the tissue in the same manner with the same method of ablation,
- Both the predicate and proposed devices are made of similar materials with long and safe histories of use, and;
- The results of the verification and validation testing:
    - Demonstrated the subject device met the predetermined performance specifications
    - Did not raise any new risks or issues of safety

VI. Performance Data

Verification testing for the thermistor circuit board modification 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 Coolrail linear pen device. The Coolrail linear pen device met the predetermined acceptance criteria ensuring substantial equivalence to the previously cleared K183065 MCR1 device. No new safety or performance issues were raising during testing.

VII. Conclusions

AtriCure has demonstrated that the Coolrail linear pen is substantially equivalent in fundamental design, technology, function, device materials, packaging, sterilization, operating principal, and intended use/ indication for use as the previously cleared Coolrail linear pen device via K183065 on 4 December 2018.
