November 4, 2019

AtriCure, Inc
Kristen Evenson
Sr. Regulatory Affairs Specialist
7555 Innovation Way
Mason, Ohio 45040

Re: K192125
Trade/Device Name: Isolator Transpolar Pen (MAX), Isolator Multifunctional Linear Pen (MLP1)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: OCL
Dated: October 16, 2019
Received: October 17, 2019

Dear Kristen Evenson:

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,

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)*
K192125

Device Name
Isolator Transpolar Pen (MAX)

Indications for Use *(Describe)*

The Isolator Transpolar Pen is a sterile, single use electro surgery device intended to ablate cardiac tissue during cardiac surgery using radiofrequency (RF) energy when connected directly to the ASU or to the ASU Source Switch in Ablation mode. When the Pen is connected to the ASU Source Switch in Auxiliary mode, it may be used for temporary cardiac sensing, recording, stimulation, and temporary pacing during the evaluation of cardiac arrhythmias.

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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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)*
K192125

Device Name
Isolator Multifunctional Linear Pen (MLP1)

Indications for Use *(Describe)*
The Isolator linear pen is a sterile, single use electro surgery device intended to ablate cardiac tissue during cardiac surgery using radiofrequency (RF) energy when connected directly to the ASU or ASB in Ablation mode.
The Isolator linear pen may be used for temporary cardiac pacing, sensing, recording, and stimulation during the evaluation of cardiac arrhythmias during surgery when connected to a temporary external cardiac pacemaker or 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.

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AtriCure®

510(k) Summary

I. Applicant Information

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

Contact Person:
Jonathan McElwee
Senior Manager, Regulatory Affairs

Alternate Contact:
Kristen Evenson
Senior Regulatory Affairs Specialist

Date Prepared:
25 July 2019

II. Device Information

Proprietary Name:
Isolator® Multifunctional Linear Pen (MLP1)
Isolator® Transpolar Pen (MAX)

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:
The devices proposed for modification in this submission are the Isolator Multifunctional Linear Pen (MLP1) cleared via K163408 on January 3, 2017, and the Isolator Transpolar Pen (MAX) cleared via K061593 on July 12, 2006.

IV. Device Description

The Isolator Multifunctional Linear Pen (MLP1) utilizes radiofrequency (RF) energy from the RF generator (ASU) to create lines of ablation on cardiac tissue. The MLP1 device is comprised of an end effector, shaft, handle, and cable. This end effector consists of one pair of ablation electrodes separated with insulating material, with the electrodes used for the pacing and sensing functions. When the Isolator Multifunctional Linear Pen is connected to an external

cardiac pacemaker or recording device, it may be used for temporary cardiac sensing, recording, stimulation, and temporary pacing during the evaluation of cardiac arrhythmias.

The Isolator Transpolar Pens (MAX1, MAX5; hereafter MAX devices) are a hand-held, single use bipolar surgical instrument intended for the ablation of cardiac tissue and for use by trained surgeons only. It is composed of a handpiece with a bipolar electrode configuration at its distal end with integral cable and a re-usable ablation and sensing unit (ASU). When a Transpolar pen is connected to an external cardiac pacemaker or recording device, it may be used for temporary cardiac sensing, recording, stimulation, and temporary pacing during the evaluation of cardiac arrhythmias.

IV. B. Intended Use/ Indications for Use

Isolator Multifunctional Linear Pen (MLP1)

"The Isolator linear pen is a sterile, single use electro surgery device intended to ablate cardiac tissue during cardiac surgery using radiofrequency (RF) energy when connected directly to the ASU or ASB in Ablation mode.

The Isolator linear pen may be used for temporary cardiac pacing, sensing, recording, and stimulation during the evaluation of cardiac arrhythmias during surgery when connected to a temporary external cardiac pacemaker or recording device."

Isolator Transpolar Pen (MAX devices)

"The Isolator Transpolar Pen is a sterile, single use electro surgery device intended to ablate cardiac tissue during cardiac surgery using radiofrequency (RF) energy when connected directly to the ASU or to the ASU Source Switch in Ablation mode.

When the Pen is connected to the ASU Source Switch in Auxiliary mode, it may be used for temporary cardiac sensing, recording, stimulation, and temporary pacing during the evaluation of cardiac arrhythmias."

AtriCure®

IV.E. Proposed Change

Each of the proposed Pen devices are designed with an end effector that consists of electrodes separated with a resin material (Sabic Cycolac Grey, manufactured by SABIC Innovative Plastics) that is used to hold the electrodes in position and act as thermal and electrical insulators. The proposed change involves implementing an alternate resin, Sabic Cycolac Grey MG37EPX-3570, for production of MAX devices and MLP1 injection molded ABS end effector components. The proposed ABS resin material is intended to be an alternate material and a full replacement upon final run-out of the previously approved resin.

IV. F Comparison of Technological Characteristics (MLP1 K163408), (MAX K061593)

- The devices have the same intended use;
- No changes were made in operating principle, or performance specifications;
- The contraindications, warnings, and precautions remain the same;
- Both the predicate and proposed alternate resin have equivalent material specifications; and
- The results of the verification and validation testing:
    - demonstrated equivalence in performance
    - demonstrated biocompatibility remains unchanged
    - did not raise any safety concerns

VI. Performance Data

Verification testing for the use of an alternate Acrylonitrile Butadiene Styrene (ABS) resin 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 devices. The Isolator Linear and Transpolar Pen devices met the predetermined acceptance criteria ensuring substantial equivalence to the previously cleared K163408 MLP1 device, and K061593 MAX device. No new safety or performance issues were raising during testing.

VII. Conclusions

AtriCure has demonstrated that the Isolator Multifunctional Linear Pen and Transpolar Pen are substantially equivalent in fundamental design, technology, function, device materials, packaging, sterilization, operating principal, and intended use/ indication for use as to the previously cleared K163408 MLP1 device, and K061593 MAX device.