DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

January 3, 2017

AtriCure Inc.
Melissa Smallwood
Associate Regulatory Affairs Specialist
7555 Innovation Way
Mason, Ohio 45040

Re: K163408
Trade/Device Name: Isolator Multifunctional Linear Pen
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: OCL
Dated: December 2, 2016
Received: December 5, 2016

Dear Melissa Smallwood:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163408

Device Name
Isolator Multifunctional Linear Pen

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.

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

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510(k) Summary

I. Submitter

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

Contact Person: Melissa Smallwood
Associate Regulatory Affairs Specialist

Alternate Contact: Jonathan McElwee
Regulatory Affairs Manager

Date Prepared: 12/02/2016

II. Device

Name of Device: Isolator® Multifunctional Linear Pen

Common Name: Surgical device, for ablation of cardiac tissue

Classification Name: 21 CFR 878 4400

Regulatory Class: Class II

Product Code: OCL

III. Predicate Device

The predicate device, Isolator Multifunctional Linear Pen, was cleared via 510(k) K130521 on April 05, 2013 under the Product Code OCL.

The predicate device has not been subject to a design-related recall.

The following reference devices were also used in this submission:

- K100501 Isolator linear pen original 510(k) cleared on June 18, 2010

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IV. Device Description

The Isolator™ linear pen System is comprised of the AtriCure® Ablation and Sensing Unit (ASU), Isolator™ linear pen (Pen), Footswitch, ASU Source Switch(ASB). The Pen is a single patient use electrosurgical instrument designed for use only with the ASU and ASB. The Pen is used to ablate cardiac tissues and as a surgical pacing and mapping tool. When the Pen is connected to the ASU, the ASU provides the bipolar radiofrequency (RF) energy flowing between both electrodes of the Pen. The Operator controls the application of this RF energy by pressing the Footswitch. When the Pen is connected to an auxiliary pace, sense, or stimulation device; the Pen is designed to provide temporary pacing or monitoring.

V. Indications for Use

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.

VI. Comparison of Technological Characteristics with the Predicate Device

- Same intended use
- Same operating principle
- No changes were made in operating principle, or specifications of performance
- The same sterilization parameters

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VII. Performance Data

Testing was completed per 21 CFR 820.30 and AtriCure's Quality System to verify the device's conformance to design controls and specification. Testing determined that the Isolator Multifunctional Linear Pen conformed to design controls and product specifications.

Non-clinical Bench Testing

- Reliability Testing

Biocompatibility Testing
The biocompatibility evaluation for the Isolator Multifunctional Linear Pen was conducted in accordance with the International Standard ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process" as recognized by FDA. The battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation
- Systemic Toxicity
- Material Mediated Pyrogen

The Isolator Multifunctional Linear Pen is categorized as a class II, "Surgical device, for ablation of cardiac tissue", for contact with "Tissue/Bone" and permanent contact for a duration of "less than 24hrs".

Per the FDA final guidance issued in 1997, 'Deciding When to Submit a 510(k) for a Change to an Existing Device', PET is listed as a material in the Biomaterials Compendium, and would not necessitate additional biocompatibility testing. AtriCure conducted confirmatory biocompatibility testing to affectively assess additional risks associated with the modification to the PET material. The results indicated no additional risk has been introduced by the modified device.

VIII. Conclusions

Based on the indications for use, technological characteristics, and safety and performance testing, the proposed AtriCure Isolator Multifunctional Linear Pen has been shown to be appropriate for its intended use and is considered substantially equivalent to the AtriCure Isolator linear pen previously cleared via 510(k) K130521 on April 05, 2013.