May 28, 2021

AtriCure, Inc.
Jon McElwee
Senior Manager, Regulatory Affairs
7555 Innovation Way
Mason, Ohio 45040

Re: K211311
Trade/Device Name: AtriCure Isolator® Synergy™ Surgical Ablation System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: OCL
Dated: April 27, 2021
Received: April 30, 2021

Dear Jon McElwee:

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,

Aneesh Deoras
Assistant Director (Acting)
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211311

Device Name
AtriCure Isolator® Synergy™ Surgical Ablation System

Indications for Use *(Describe)*
The AtriCure Isolator Synergy Surgical Ablation System is intended to ablate cardiac tissue during surgery.

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: 513-498-5067
F: 513-895-9013

Contact Person: Jonathan McElwee, RAC
Sr. Manager, Regulatory Affairs

Alternate Contact: Mary Galeano
Sr Regulatory Affairs Specialist

Date Prepared: 04/29/2021

II. Device Information

Proprietary Name: AtriCure Isolator® Synergy™ Surgical Ablation System

Common Name: Cardiac Radio Frequency Ablation System Clamps

Classification: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II; per 21 CFR 878.4400
Product Code: OCL
Classification Panel: Card ovascular

Predicate Device: AtriCure Bipolar System (EMR2, EML2) (K110117, April 8, 2011)

III. Device Description

The AtriCure Isolator Synergy Surgical Ablation System is comprised of the Ablation and Sensing Unit (ASU), AtriCure Switch Matrix (ASB), an AtriCure Isolator Synergy device, and a footswitch. The AtriCure Isolator Synergy device is a single-patient use, electrosurgical instrument designed for use only with the ASU.

The AtriCure Isolator Synergy clamp is used for cardiac tissue ablation. When activated, the ASU delivers radiofrequency (RF) energy to the linear electrodes on the insulated jaws of the AtriCure Isolator Synergy Clamp. The Operator controls the application of this RF energy by pressing the Footswitch.

All AtriCure Isolator Synergy devices are configured as vascular clamps and feature clamping jaws of various lengths, curvatures and apertures; rounded jaw tips, and cables that plugs into the ASB switch matrix and ASU RF generator.

The AtriCure Isolator Synergy Clamps features two pairs of opposing dual electrodes, an in-line handle with syringe-type grip handle/ actuation and button release mechanisms.

There is a Glidepath™ Tape Guide that is a single-patient use, detachable, surgical device designed to facilitate the guidance of surgical instruments through soft tissue during general surgical procedures. The Guide is package with ISOLATOR devices that have the Attachment Tip.

The Glidepath Tape Instrument Guide is a single-patient use, surgical device designed to facilitate the guidance of surgical instruments through soft tissue during general surgical procedures.

NOTE: Please refer to the AtriCure ASU2 and ASB3 Instructions for Use for information specific to the ASU2 and ASB3.

IV. Indications for Use

The AtriCure Isolator Synergy Surgical Ablation System is intended to ablate cardiac tissue during surgery.

V. Comparison of Technological Characteristics (Isolator Synergy Clamp –K110117)

This submission included modifications to allow for an alternate insulator resin and alternate end effector design change to an overmold configuration. The science and fundamental technology of the Isolator Synergy Clamps (EMR2, EML2) in comparison to the predicate Isolator Synergy Clamp (EMR2, EML2), cleared per K110117, remain the same. Performance testing confirmed that the Isolator Synergy Clamps meets the same requirements for safety and efficacy as the predicate Isolator Synergy Clamp.

Table 1: Device Comparison

#	Category	Feature/Item	Current - Isolator Synergy Clamps (EMR2, EML2)	Proposed Isolator Synergy Clamps (EMR2, EML2)	Equivalence Comparison
1	General Information	**Manufacturer**	AtriCure, Inc.	AtriCure, Inc.	Same
2		**Product Name**	Isolator Synergy Clamp with Glidepath soft guide	Isolator Synergy Clamp with Glidepath soft guide	Same
3		**510(k) and Past Submission References**	K110117	K211311	N/A
4		**Device Classification / Product Code**	Class II, 21 CFR § 878.4400 OCL	Class II, 21 CFR § 878.4400 OCL	Same
5		**Model Number**	EMR2, EML2	EMR2, EML2	N/A
6		**Indications for Use**	The System is intended for the ablation of cardiac tissue during surgery.	The System is intended for the ablation of cardiac tissue during surgery.	Same
7		**Contraindication**	The Bipolar (Transpolar) System is not indicated for contraceptive coagulation of the fallopian tubes.	The Bipolar (Transpolar) System is not indicated for contraceptive coagulation of the fallopian tubes.	Same
8		**Device Description**	Electrosurgical Bipolar RF Clamp and optional accessory (Class I) instrument guide	Electrosurgical Bipolar RF Clamp and optional accessory (Class I) instrument guide	Same
9		**Generator Description/ Energy Source**	RF Generator – Ablation and Sensing Unit and Source Switch Matrix (ASU2, ASB3)	RF Generator – Ablation and Sensing Unit and Source Switch Matrix (ASU2, ASB3)	Same
10		**Accessory/ Positioning Guide**	Product Name: Glidepath Tape Materials: Santoprene 8000 Thermoplastic Rubber with Ultem pins	Product Name: Glidepath Tape Materials: Santoprene 8000 Thermoplastic Rubber with Ultem pins	Same

#	Category	Feature/Item	Current - Isolator Synergy Clamps (EMR2, EML2)	Proposed Isolator Synergy Clamps (EMR2, EML2)	Equivalence Comparison
		End Effector Design	Non-overmolded design with ABS resin MG37EP	Overmolded design with ABS resin MG37EPX	Equivalent
11	**Performance**	**Ablation Performance – Transmurality**	Transmural lesions	Transmural lesions	Same
12		**Ablation Performance – Lesion Width**	Lesions tightly confined to the region between the opposing insulated jaws.	Lesions tightly confined to the region between the opposing insulated jaws.	Same
13	**Sterilization and Other**	**Sterilization Site**	EO	EO	Same
14		**Packaging**	PETG blister with Tyvek® lid	PETG blister with Tyvek® lid	Same
15		**Sterilization**	Ethylene Oxide	Ethylene Oxide	Same
16		**Sterility Assurance Level**	10^{-6} SAL	10^{-6} SAL	Same
17		**Biocompatibility**	Meets requirements of ISO 10993	Meets requirements of ISO 10993	Same
18		**Shelf Life**	3 year	3 year	Same
19		**Pyrogen**	Non-pyrogenic	Non-pyrogenic	Same
20		**Latex**	Not made with natural rubber latex	Not made with natural rubber latex	Same
21		**Software**	No software in the clamp	No software in the clamp	Same

VI. Performance Data

A review of the risk analysis concluded there is not overall change to the risk profile of the proposed AtriCure Isolator Synergy clamps versus the previously cleared AtriCure Isolator Synergy clamps as the modifications to the proposed AtriCure Isolator Synergy do not add or remove any features of the device or change the clinical application.

The proposed changes do not include any change to design or performance specifications of the AtriCure Isolator Synergy clamps. Additionally, the proposed changes did not modify the intended use, therefore the previously submitted bench and animal data remain valid for the AtriCure Isolator Synergy clamps.

The following consensus standards were leveraged in this submission:

- ISO 10993-1
- IEC 60601-2-2
- ASTM E1952-11
- ISO 11607-2
- AAMI TIR 28

Biocompatibility Testing

The biocompatibility evaluation is 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. Data collected from the following tests support this change:

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic Toxicity
- Material Mediated Pyrogenicity

VII. Conclusions

AtriCure has demonstrated that the modifications made to the Isolator Synergy Clamp (EMR2, EML2) are substantially equivalent in intended use/indication for use as the previously cleared Isolator Synergy Clamp (EMR2, EML2) per K110117.