July 26, 2021

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

Re: K210477
Trade/Device Name: Isolator® Synergy™ EnCompass Clamp (OLH, OSH) and Guide (GPM100) System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: OCL
Dated: June 21, 2021
Received: June 21, 2021

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. 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)*
K210477

Device Name
Isolator® Synergy™ EnCompass Clamp (OLH, OSH) and Guide (GPM100) system

Indications for Use *(Describe)*
The AtriCure Isolator Synergy EnCompass Clamp and Guide 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: Melissa Smallwood, MHA
Manager, Regulatory Affairs

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

Date Prepared: 07/22/2021

II. Device Information

Proprietary Name: Isolator® Synergy™ EnCompass Clamp (OLH, OSH) and Guide (GPM100) 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: Cardiovascular

Predicate Device: Isolator Synergy Dual Electrode Clamp (EMR2/EML2/EMT)
(K110117, OCL, April 8, 2011)

III. Device Description

The CLAMP is a single-use electrosurgical instrument offered in two configurations: standard length jaws (OSH), and long length jaws (OLH). All Isolator devices are configured as vascular clamps and feature clamping jaws of various lengths and curvatures. The AtriCure Isolator clamps feature an in-line handle with syringe-type actuation and button release mechanisms.

The GUIDE is a single-use surgical accessory designed to facilitate the guidance of surgical instruments through tissue during cardiothoracic surgical procedures. The GUIDE has a flexible, malleable shaft, and magnetic attachment ends that connect to the metal tip of the CLAMP jaws inside the jaw magnet cups.

IV. Intended Use/ Indications for Use

The AtriCure Isolator Synergy EnCompass Clamp and Guide system is intended to ablate cardiac tissue during surgery.

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V. Comparison of Technological Characteristics

The science and fundamental technology of the Isolator Synergy EnCompass Clamp (OLH, OSH) and Guide (GPM100) in comparison to the predicate Isolator Synergy Dual Electrode Clamp (EMR2/EML2), cleared per K110117, remain the same and include a longer jaw in comparison to the predicate to allow for surgeon preference and body habitus.. A comparison of the Isolator Synergy EnCompass Clamp (OLH, OSH) and Guide (GPM100) technological characteristics as compared to the predicate Isolator Synergy Dual Electrode Clamp (EMR2/EML2) are provided in **Table 1** below:

Table 1: Comparison of Technological Characteristics

Feature	Predicate (K110117) Isolator Synergy Dual Electrode Clamp (EMR/ EML2)	Subject Isolator Synergy EnCompass Clamp (OLH, OSH) and Guide (GPM100)	Equivalence Comparison
Proprietary Name	Isolator Synergy Dual Electrode Clamp	Isolator Synergy EnCompass Clamp and Guide	N/a
Model Numbers	EMR2, EML2	OLH, OSH	N/a
Indications for Use	The ATRICURE Bipolar (Transpolar) System is intended to ablate cardiac tissue during surgery.	The Isolator Synergy EnCompass Clamp and Guide system is intended to ablate cardiac tissue during surgery.	Same
Device Description in Instructions for Use	The AtriCure ISOLATOR Synergy Surgical Ablation System is comprised of the Ablation and Sensing Unit (ASU), an AtriCure ISOLATOR Synergy device, and a footswitch. The ISOLATOR is a single patient use electrosurgical instrument designed for use only with the ASU. The ISOLATOR is used for cardiac tissue ablation. When activated, the ASU delivers radiofrequency (RF) energy to the linear electrodes on the insulated jaws of the ISOLATOR. The Operator controls the application of this RF energy by pressing the Footswitch. All ISOLATOR Synergy devices are configured as vascular clamps and feature clamping jaws of various lengths and curvatures. The AtriCure ISOLATOR Synergy Clamps feature an in-line handle with syringe-type actuation and button release mechanisms. The Guide is packaged with ISOLATOR devices that have the Attachment Tip. The GLIDEPATH™ Tape Instrument Guide is a single patient, surgical device designed	The CLAMP is a single-use electrosurgical instrument offered in two configurations: standard length jaws (OSH), and long length jaws (OLH). All Isolator devices are configured as vascular clamps and feature clamping jaws of various lengths and curvatures. The AtriCure Isolator clamps feature an in-line handle with syringe-type actuation and button release mechanisms. The GUIDE is a single-use surgical accessory designed to facilitate the guidance of surgical instruments through tissue during cardiothoracic surgical procedures. The GUIDE has a flexible, malleable shaft, and magnetic attachment ends that connect to the metal tip of the CLAMP jaws inside the jaw magnet cups.	Similar, added reference to OSH, OLH, and GPM100. Removed reference to EMR2, EML2. The Isolator Synergy EnCompass Clamp and Guide have the same intended use as the predicate Isolator Synergy Dual Electrode Clamp.

	to facilitate the guidance of surgical instruments through soft tissue during general surgical procedures.		
Clamp Design	Vascular clamps featuring clamping jaws with left and right curvature, designed with parallel closure throughout clamping motion.	Vascular clamps featuring clamping jaws of various lengths, designed with lengthened end effector, and hinge to parallel closure in range of tissue clamping as compared to predicate.	Similar, orientation and length modifications provide additional options based on patient body habitus and surgeon preference.
Positioning / Guide	Glidepath Tape (GPT100)	Glidepath Magnetic (GPM100)	Similar, GPM100 guide supports positioning of the clamp using magnetic tips as compared to snap fit feature.
Generator/RF Energy	Bipolar radiofrequency energy generated by ASU2	Bipolar radiofrequency energy generated by ASU2	Same
Biocompatibility	Biocompatible patient contacting materials per ISO 10993	Biocompatible patient contacting materials per ISO 10993	Same
Packaging	PETG blister with Tyvek® lid	PETG blister with Tyvek® lid	Same
Sterilization	Ethylene Oxide SAL 10^{-6}	Ethylene Oxide SAL 10^{-6}	Same

Performance testing as identified in Section VI, was conducted and confirmed that the difference in technological characteristics between the Isolator Synergy EnCompass Clamp and Guide and the predicate Isolator Synergy Dual Electrode do not affect safety and effectiveness of the device.

VI. Performance Data

The following bench testing was conducted for design and performance elements deemed appropriate to demonstrate equivalence of the Isolator Synergy EnCompass Clamp (OLH, OSH) and Guide (GPM100) to the previously cleared Isolator Synergy Dual Electrode Clamp (EMR2/EML2). The Isolator Synergy EnCompass Clamp (OLH, OSH) and Guide (GPM100) met the predetermined acceptance criteria ensuring substantial equivalence to the previously cleared Isolator Synergy Dual Electrode Clamp (EMR2/EML2). No new safety or performance issues were raising during testing.

Non-clinical Performance Testing:

- Mechanical Testing
- *Ex vivo* Ablation Comparison Testing
- Reliability Testing
- External Surface Temperature Testing
- *GLP Animal Study*
- Biocompatibility Testing
- Shelf Life Testing
- Electrical Safety Testing

VII. Conclusions

AtriCure has demonstrated that the modifications made to the Isolator Synergy EnCompass Clamp (OLH, OSH) and Guide (GPM100) are substantially equivalent in fundamental design, technology, function, device materials, packaging, sterilization, operating principle, and intended use / indication for use as the previously cleared Isolator Synergy Dual Electrode Clamp (EMR2/EML2/EMT) per K110117.
