August 27, 2024

AtriCure Inc.
Dominique Neisz
Manager, Regulatory Affairs
7555 Innovation Way
Mason, Ohio 45040

Re: K234151
Trade/Device Name: AtriCure Isolator Synergy EnCapture Ablation System (EMH)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: OCL
Dated: August 7, 2024
Received: August 7, 2024

Dear Dominique Neisz:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 S. Deoras -S

Aneesh Deoras
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K234151

Device Name

AtriCure Isolator Synergy EnCapture Ablation System (EMH)

Indications for Use *(Describe)*

The AtriCure Isolator Synergy EnCapture Clamp 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: Dominique Neisz
Manager, Regulatory Affairs

Alternate Contact: Jim Taufen
Director, Regulatory Affairs

Date Prepared: December 29th, 2023

II. Device Information

Proprietary Name: AtriCure Isolator Synergy EnCapture Ablation System (EMH)

Common Name: Cardiac Radio Frequency Ablation System Clamp

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™ Surgical Ablation System (EMR2/EML2)
(K211311, OCL, May 28th, 2021)

Reference Device: DeBakey Satinsky Atrauma Tangential Occlusion Clamp
(K123077, DXC, May 14th, 2013)

III. Device Description

The AtriCure Isolator Synergy EnCapture Clamp (referred to hereafter as CLAMP) is a single patient use electrosurgical instrument designed for use with an AtriCure RF GENERATOR. The CLAMP is used for cardiac tissue ablation. When activated, the GENERATOR delivers radiofrequency (RF) energy to the linear electrodes on the insulated jaws of the device. The Operator controls the application of this RF energy by pressing the Footswitch. The CLAMP features two pairs of opposing dual electrodes, an in-line handle with syringe-type actuation and button release mechanism. The device outer and ablative faces of the distal jaw segments have textured surfaces to increase the engagement between the jaw face and the cardiac tissue. The CLAMP is compatible with the Glidepath Tape Instrument (hereafter known as GUIDE), that is designed to attach to the fixed jaw of the CLAMP with a half turn attachment end connection. The GUIDE is a single-patient, optional component designed to facilitate the guidance of the CLAMP around target tissue during general surgical procedures.

IV. Intended Use/ Indications for Use

The AtriCure Isolator Synergy EnCapture Clamp is intended to ablate cardiac tissue during surgery.

V. Comparison of Technological Characteristics

The science and fundamental technology of the Isolator Synergy EnCapture Ablation System (EMH) in comparison to the predicate Isolator Synergy Surgical Ablation System (EMR2/EML2), cleared per K211311, remain the same and include an angled jaw in comparison to the predicate to allow for surgeon preference and body habitus. A comparison of the Isolator Synergy EnCapture Ablation System (EMH) technological characteristics as compared to the predicate Isolator Synergy Surgical Ablation System (EMR2/EML2) are provided in **Table 1** below:

Table 1: Comparison of Technological Characteristics

Feature	**Predicate (K211311) Isolator Synergy Surgical Ablation System (EMR2/EML2)**	**Subject Isolator Synergy EnCapture Ablation System (EMH)**	**Equivalence Comparison**
Proprietary Name	ATRICURE Bipolar (Transpolar) System	AtriCure Isolator Synergy EnCapture Ablation System (EMH)	Same
Model Numbers	EMR2	EMH	N/a
Indications for Use	The ATRICURE Bipolar (Transpolar) System is intended to ablate cardiac tissue during surgery.	The AtriCure Isolator Synergy EnCapture Clamp is intended to ablate cardiac tissue during surgery.	Same
Clamp Design	Clamps featuring clamping jaws with left and right curvature, designed with parallel closure throughout clamping motion.	Clamp featuring textured clamping jaws designed with right angled end effector, and hinge to parallel closure in range of tissue clamping as compared to predicate.	Similar, orientation, jaw geometry and texture modifications provide additional options based on patient body habitus and surgeon preference.
Positioning / Guide	Supplied with Glidepath Tape Instrument Guide (GPT100)	Supplied separately, compatible with Glidepath Tape Instrument Guide (GPT200)	Similar, GPT200 guide supports positioning of the clamp if desired by user using half-turn connection as compared to snap fit feature.
Generator/RF Energy	Bipolar radiofrequency energy generated by ASU2 or MAG	Bipolar radiofrequency energy generated by ASU2 or MAG	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 was conducted and confirmed that the difference in technological characteristics between the Isolator Synergy EnCapture Ablation System (EMH) and the predicate Isolator Synergy Surgical Ablation System (EMR2/EML2) does not introduce different questions of safety and effectiveness. Inclusion of a textured surface on the subject device was supported by a reference device with textured jaws commonly used in cardiovascular procedures (DeBakey Satinsky Vascular Clamp).

VI. Performance Data

The following bench testing was conducted for design and performance elements deemed appropriate to demonstrate substantial equivalence of the Isolator Synergy EnCapture Ablation System (EMH) to the previously cleared Isolator Synergy Surgical Ablation System (EMR2/EML2).

Non-clinical Performance Testing:

- Mechanical Testing
- *Ex vivo* Ablation Comparison Testing
- Reliability Testing
- External Surface Temperature Testing
- *In-vivo GLP Animal Study*
- Biocompatibility Testing
- Shelf-Life Testing
- Electrical Safety Testing & Electromagnetic Compatibility (EMC)

Mechanical Testing

- Jaw Aperture Testing
- Clamp Force Testing
- Handle Closure Force Testing

In Vivo GLP Animal Study

A 7-day subacute animal study was conducted, 12 pigs underwent median sternotomy and received ablations on targeting clinically relevant structures. 6 pigs were utilized for the control group with the use of the Isolator Synergy Surgical Ablation System (EMR2/EML2), while the remaining 6 pigs were ablated with the Isolator Synergy EnCapture Ablation System (EMH). There were no procedure related complications attributed to the control or subject device. The pigs were evaluated 7 days post-op for evidence of conduction block and evidence of adverse effects. In addition, macroscopic and microscopic analysis was performed to complete pathology and histology endpoints of the study objective.

Results of the sub-acute animal study demonstrated the Isolator Synergy EnCapture Ablation System (EMH) can create transmural lesions on intended cardiac structures in a substantially equivalent manner as compared to the predicate Isolator Synergy Surgical Ablation System (EMR2/EML2).

Biocompatibility Testing

The biocompatibility evaluation of the Isolator Synergy EnCapture Clamp was conducted in accordance with ISO 10993-1:2018, “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
- Acute Systemic Toxicity
- Material Mediated Pyrogenicity

The Isolator Synergy EnCapture Clamp is categorized as an externally communicating device with tissue and/or bone contact and limited duration (≤24 hours). Results demonstrated there were no new or increased biocompatibility risks and the Isolator Synergy EnCapture Clamp complies with ISO 10993-1:2018.

Electrical Safety Testing & Electromagnetic Compatibility (EMC)

Electrical safety and EMC testing were conducted on the Isolator Synergy EnCapture Ablation System (EMH), consisting of the RF Handpiece and RF Generator. The system complies with IEC 60601-1:2005+A1:2012+A2:2020 Ed. 3.2 “General requirements for basic safety and essential performance” and IEC 60601-1-2:2014+A1:2020 “Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance.”

The Isolator Synergy EnCapture Clamp (EMH) met the predetermined acceptance criteria ensuring substantial equivalence to the previously cleared Isolator Synergy Surgical Ablation System (EMR2/EML2). No new safety or performance issues were raised during testing.

VII. Conclusions

AtriCure has demonstrated that the Isolator Synergy EnCapture Ablation System (EMH) is 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 Surgical Ablation System (EMR2/EML2) per K211311.