July 24, 2025

AtriCure, Inc.
Ingrid Dirtzu
Senior Regulatory Affairs Specialist
7555 Innovation Way
Mason, Ohio 45040

Re: K252056
Trade/Device Name: Isolator® Synergy™ EnCompass Clamp and Guide System (OLH, OSH, GPM100)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: OCL
Dated: June 30, 2025
Received: July 1, 2025

Dear Ingrid Dirtzu:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252056

Please provide the device trade name(s).

Isolator® Synergy™ EnCompass Clamp and Guide System (OLH, OSH, GPM100)

Please provide your Indications for Use below.

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

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

I. Applicant Information

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

Contact Person: Ingrid Dirtzu
Sr. Specialist, Regulatory Affairs
C: 651-246-8589

Alternate Contact: Dominique Neisz
Manager, Regulatory Affairs
C: 612-275-5499

Date Prepared: 30 June 2025

II. Device Information

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

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™ EnCompass Clamp (OLH, OSH) and Guide (GPM100) System (K210477, OCL, cleared 28 May 2021)

III. Device Description

The Isolator Synergy EnCompass Clamp and Guide System (OLH, OSH, GPM100) is a single-use electrosurgical instrument offered in two configurations: standard length jaws (OSH), and long length jaws (OLH), each with an accessory Glidepath Magnetic Guide (GPM100). All Isolator devices are configured as vascular clamps and feature clamping jaws of various lengths and curvatures. The clamp features two pairs of opposing dual electrodes, an in-line handle with syringe-type actuation and button release mechanism. 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 connected to the generator. 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.

V. Comparison of Technological Characteristics

The science and fundamental technology of the proposed Isolator Synergy EnCompass Clamp and Guide System (OLH, OSH, GPM100), in comparison to the predicate Isolator Synergy EnCompass Clamp (OLH, OSH) and Guide (GPM100) System, cleared per K210477, remain the same. The proposed device, which is the subject of this 510(k) submission, features minor geometry changes in the Glidepath Magnetic Guide and the connector for the guide to accommodate a better connection between the clamp and guide. Additional changes in geometry have been made to accommodate changes to manufacturing technologies, including overmolding and metal-injection molding. Updates have been made to the instructions for use, breaking certain procedural steps into several smaller steps to provide the user with greater detail, and aligning the placement of warnings and precautions more closely with these steps. Several warnings have been introduced as controls for previously identified risks, but no new risks or significantly modified risks have been identified.

A comparison of the predicate and proposed Isolator Synergy EnCompass Clamp and Guide System (OLH, OSH, GPM100) technological characteristics are provided in **Table 1** below:

Table 1: Comparison of Technological Characteristics

#	Feature	Predicate Device (K210477)	Subject Device	Equivalence/ Comparison
1	Proprietary Name	Isolator Synergy EnCompass Clamp and Guide System	Isolator Synergy EnCompass Clamp and Guide System	Same
2	Model Numbers	OLH, OSH, GPM100	OLH, OSH, GPM100	Same
3	Device Classification	21 CFR 878.4400 Product Code: OCL	21 CFR 878.4400 Product Code: OCL	Same
4	Regulatory Class	Class II	Class II	Same
5	FDA Division	General and Cardiovascular Surgery	General and Cardiovascular Surgery	Same
6	Indications for Use	The AtriCure Isolator Synergy EnCompass Clamp and Guide System is intended to ablate cardiac tissue during surgery.	The AtriCure Isolator Synergy EnCompass Clamp and Guide System is intended to ablate cardiac tissue during surgery.	Same
7	Contraindications	The AtriCure Isolator Synergy EnCompass Clamp and Guide System is not indicated for contraceptive coagulation of the fallopian tubes.	The AtriCure Isolator Synergy EnCompass Clamp and Guide System is not indicated for contraceptive coagulation of the fallopian tubes.	Same
8	Clamp Design	The Isolator Synergy EnCompass device is configured as a vascular clamp with a hexagonal jaw, offered in two different lengths featuring D-shaped magnet cups a the jaw tips to connect to the Guide. The clamps feature an in-line handle with syringe-type actuation and button release mechanisms. The clamp connects to a reusable bipolar radiofrequency (RF) generator via the integrated cable which supplies energy to the two pairs of	The Isolator Synergy EnCompass device is configured as a vascular clamp with a hexagonal jaw, offered in two different lengths, featuring cylindrical magnet cups at the jaw tips to connect to the Guide. The clamps feature an in-line handle with syringe-type actuation and button release mechanisms. The clamp connects to a reusable bipolar radiofrequency (RF) generator via the integrated cable which supplies energy to the two pairs of	Similar; while the fundamental design of the device has not changed, the subject device features a change from D-shaped to cylindrical magnet cups to connect to the GPM100, while maintaining the same connection

		electrodes housed on the fixed and articulating jaws of the clamp.	electrodes housed on the fixed and articulating jaws of the clamp.	strength. Additionally, the subject device features minor geometry changes to the jaws and insulators in order to accommodate the overmolding and metal-injection molding processes.
9	Positioning / Guide	Supplied with Glidepath Magnetic Guide (GPM100)	Supplied with Glidepath Magnetic Guide (GPM100)	Similar; the Guide which is supplied with the subject devices features a tapering of the ends of the red santoprene, while maintaining the same overall length.
10	Generator/RF Energy	Bipolar radiofrequency energy generated by ASU2/ASB2 or MAG	Bipolar radiofrequency energy generated by ASU2/ASB2 or MAG	Same
11	Biocompatibility	Biocompatible patient contacting materials per ISO 10993	Biocompatible patient contacting materials per ISO 10993	Same
12	Packaging	PETG blister with Tyvek® lid	PETG blister with Tyvek® lid	Same
13	Sterilization	Ethylene Oxide SAL 10-6	Ethylene Oxide SAL 10-6	Same
14	Pyrogen	Non-Pyrogenic	Non-Pyrogenic	Same

The devices have the same intended use. No changes were made in operating principle. No changes were made to the overall design or function of the device.

VI. Performance Data

Performance testing was conducted and confirmed that the difference in technological characteristics between the proposed Isolator Synergy EnCompass Clamp and Guide System (OLH, OSH, GPM100) and the predicate do not impact the safety and effectiveness of the device.

The following bench testing was conducted for design and performance elements deemed appropriate to demonstrate substantial equivalence of the Isolator Synergy EnCompass Clamp and Guide System (OLH, OSH, GPM100) to the previously cleared Isolator Synergy EnCompass Clamp (OLH, OSH) and Guide (GPM100) System.

Mechanical Testing

- Jaw Aperture Testing
- Clamp Force Testing
- Handle Closure Force Testing
- Device-to-Guide Pull Force Testing
- Snag Testing

Non-clinical Performance Testing:

- *Ex vivo* Ablation Comparison Testing
- Lifecycle (Reliability) Testing
- Usability Testing
- Biocompatibility Testing
- Electrical Safety Testing
- Sterilization Validation

Ex Vivo Ablation Comparison Testing

The proposed Isolator Synergy EnCompass Clamp and Guide System (OLH, OSH, GPM100) underwent performance testing with bovine tissue, using the outer bounds of the range of tissue thicknesses for use with the device in order to evaluate lesion width and lesion transmurality. Results of this testing demonstrate that the Isolator Synergy EnCompass Clamp and Guide System (OLH, OSH, GPM100) with the proposed modifications creates transmural lesions in a substantially equivalent manner as compared to the predicate Isolator Synergy Synergy EnCompass Clamp (OLH, OSH) and Guide (GPM100) System.

Lifecycle Reliability Testing

Reliability testing was performed to evaluate the design life of the proposed device, and to confirm that the proposed design life for single patient use under normal use conditions is unaffected. The Design Life requirement includes the plug/unplug cycle of the clamp from the generator, along with a specified number of ablations to transmurality, while demonstrating electrical continuity and isolation, as well as the physical integrity of the device (e.g. no signs of breakdown). The proposed Isolator Synergy EnCompass Clamp and Guide System (OLH, OSH, GPM100) met the predetermined acceptance criteria, ensuring substantial equivalence to the previously cleared Isolator Synergy EnCompass Clamp (OLH, OSH) and Guide (GPM100) System. No new safety or performance issues were raised during testing.

Usability Testing

Usability testing was conducted to validate the changes to the proposed device via a simulated use scenario in a cadaver lab documenting the participants' ability to maneuver the clamp and access the desired tissue planes using the proposed device. Zero use errors, close calls, or use difficulties were observed during the simulation, supporting the assessment that the use of the device is unaffected by the changes proposed, and that no new risks are introduced by these changes. No new risks were identified and no changes to the existing ratings were identified as a result of this change.

Biocompatibility Testing

The biocompatibility evaluation of the Isolator Synergy EnCompass Clamp and Guide System (OLH, OSH, GPM100) 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 EnCompass Clamp and Guide System (OLH, OSH, GPM100) 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 proposed Isolator Synergy EnCompass Clamp and Guide System (OLH, OSH, GPM100) complies with ISO 10993-1:2018.

Electrical Safety Testing
Electrical safety was conducted on the proposed Isolator Synergy EnCompass Clamp and Guide System (OLH, OSH, GPM100), 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 60601-2-2:2014+A1:2020 "Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance."

The proposed Isolator Synergy EnCompass Clamp and Guide System (OLH, OSH, GPM100) met the predetermined acceptance criteria ensuring substantial equivalence to the previously cleared Isolator Synergy EnCompass Clamp (OLH, OSH) and Guide (GPM100) System. No new safety or performance issues were raised during testing.

Sterilization Validation
Validation for the proposed sustainable (reduced) EO sterilization cycle (Steris Cycle 1511A) was conducted at Steris Isomedix Operation (Spartanburg, SC) using the half-cycle (overkill) method per the recognized standard ANSI/AAMI/ISO 11135, Medical devices – validation and routine control of ethylene oxide sterilization. The sustainable EO cycle has been demonstrated to achieve the same Sterility Assurance Level (SAL) 10-6 as the predicate and has been validated in accordance with ISO 11135 and residuals for both EO and ECH have been evaluated to the requirements of the recognized standard ANSI/AAMI/ISO 10993-7 Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals. Endotoxin-mediated pyrogenicity is demonstrated by LAL testing conducted with each sterilization batch.

VII. Conclusions

AtriCure has demonstrated that the modifications made to the Isolator Synergy EnCompass Clamp and Guide System (OLH, OSH, 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 EnCompass Clamp (OLH, OSH) and Guide (GPM100) System per K210477.
