December 30, 2022

AtriCure, Inc
Jonathan McElwee
Director, Regulatory Affairs
7555 Innovation Way
Mason, Ohio 45040

Re: K221358
Trade/Device Name: Isolator® Linear Pen (MLP1); Isolator® Transpolar™ Pen (MAX1, MAX5), Coolrail® Linear Pen (MCR1); Isolator® Synergy Surgical Ablation System (EMR2, EML2); Isolator® Synergy™ EnCompass Clamp (OLH, OSH) and Guide System; Isolator® Synergy Access Clamp (EMT1)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: OCL
Dated: May 9, 2022
Received: May 11, 2022

Dear Jonathan 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 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221358

Device Name
Isolator® Linear Pen (MLP1)

Indications for Use *(Describe)*
The Isolator linear pen is a sterile, single use electrosurgery device intended to ablate cardiac tissue during cardiac surgery using radiofrequency (RF) energy when connected directly to the ASU/ASB or MAG 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)

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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)*
K221358

Device Name
Isolator® Transpolar™ Pen (MAX1, MAX5)

Indications for Use *(Describe)*
The Isolator Transpolar Pen is a sterile, single use electrosurgery device intended to ablate cardiac tissue during cardiac surgery using radiofrequency (RF) energy.

The Isolator Transpolar 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)

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Indications for Use

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See PRA Statement below.

510(k) Number *(if known)*
K221358

Device Name
Coolrail® Linear Pen (MCR1)

Indications for Use *(Describe)*
The Coolrail® linear pen is a sterile, single use electrosurgery device intended to ablate cardiac tissue during cardiac surgery using radiofrequency (RF) energy.

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)

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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221358

Device Name
Isolator® Synergy Surgical Ablation System (EMR2, EML2)

Indications for Use *(Describe)*
The AtriCure Bipolar (Transpolar) 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)

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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221358

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

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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221358

Device Name
Isolator® Synergy Access® Clamp (EMT1)

Indications for Use *(Describe)*
The AtriCure Bipolar (Transpolar) 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)

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AtriCure®

510(k) Summary

I. Applicant Information

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

Contact Person: Jonathan McElwee
Director, Regulatory Affairs

Alternate Contact: Dennis Hong
Vice President, Regulatory Affairs

Date Prepared: 01 December 2022

II. Device Information

Proprietary Names: Isolator® Linear Pen (MLP1)
Isolator® Transpolar™ Pen (MAX1, MAX5)
Coolrail® Linear Pen (MCR1)
Isolator® Synergy Surgical Ablation System (EMR2, EML2)
Isolator® Synergy™ EnCompass Clamp (OLH, OSH) and Guide System
Isolator® Synergy Access® Clamp (EMT1)

Common Name: Electrosurgical device

Classification: Surgical device for cutting, coagulation, and/or ablation of tissue, including cardiac tissue
Regulatory Class: Class II; per 21 CFR 878.4400
Product Code: OCL
Classification Panel: Cardiovascular

Predicate Devices:

- Isolator® Linear Pen (MLP1) cleared via K192125 on November 4, 2019
- Isolator® Transpolar Pen (MAX1, MAX5) cleared via K192125 on November 4, 2019
- Coolrail® Linear Pen (MCR1) cleared via K190587 on July 24, 2019
- Isolator® Synergy Surgical Ablation System (EMR2, EML2) cleared via K211311 on May 28, 2021
- Isolator® Synergy EnCompass Clamp (OLH, OSH) and Guide System cleared via K210477 on July 26, 2021
- Isolator® Synergy Access Clamp (EMT1) cleared via K110117 on April 8, 2011.

III. Device Description

The Isolator Linear Pen (MLP1) utilizes radiofrequency (RF) energy from a RF generator to create lines of ablation on cardiac tissue. The MLP1 device is comprised of an end effector, shaft, handle, and cable. This end effector consists of one pair of ablation electrodes separated with insulating material, with the electrodes used for the pacing and sensing functions. When the Isolator linear pen is connected to an external cardiac pacemaker or recording device, it may be used for temporary cardiac sensing, recording, stimulation, and temporary pacing during the evaluation of cardiac arrhythmias.

The Isolator Transpolar Pen (MAX1, MAX5) is a hand-held, single use bipolar surgical instrument intended for the ablation of cardiac tissue and for use by trained surgeons only. It is composed of a handpiece with a bipolar electrode configuration at its distal end with integral cable and is powered by a radiofrequency (RF) generator. When the Transpolar pen is connected to an external cardiac pacemaker or recording device, it may be used for temporary cardiac sensing, recording, stimulation, and temporary pacing during the evaluation of cardiac arrhythmias.

The Coolrail Linear Pen (MCR1) is a hand-held, single use surgical instrument intended for the ablation of cardiac tissues during cardiac surgery. The pen utilizes bipolar energy generated by a radiofrequency (RF) generator. The Coolrail linear pen is designed with internally cooled electrodes to reduce thermal heating allowing for the energy to traverse deeper and more consistently into the target tissue. The ASU delivers bipolar RF energy, which flows between the internally cooled electrodes of the Coolrail linear pen. The Operator controls the application of energy by pressing the footswitch.

The Isolator Synergy Clamps (EMR2, EML2) are single-patient use, electrosurgical instruments designed for use with a radiofrequency (RF) generator and are indicated to ablate cardiac tissue. 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. The AtriCure Isolator Synergy Clamps feature two pairs of opposing dual electrodes, an in-line handle with syringe-type grip handle/ actuation and button release mechanisms.

The Isolator Synergy EnCompass Clamps (OLH, OSH) are a single-use electrosurgical instrument offered in two configurations: standard length jaws (OSH), and long length jaws (OLH). The AtriCure Isolator clamps feature an in-line handle with syringe-type actuation and button release mechanisms. The clamps utilize bipolar energy generated from a radiofrequency (RF) generator.

The Isolator Synergy Access Clamp (EMT1) is a handheld, single use, bipolar radiofrequency (RF) surgical instrument intended for the ablation of cardiac tissue. EMT1 is part of the AtriCure Bipolar (Transpolar) System which includes an accessory instrument guide (Glidepath Tape). The EMT1 clamp is connected via an integral cable to a radiofrequency (RF) generator.

The ASU/ASB Generator is the original RF energy source for the cleared handpieces listed above. The ASU/ASB Generator will continue to be available for use and is unchanged from the original clearances.

The Multifunctional Ablation Generator (MAG) is an alternate RF energy source to the currently cleared ASU/ASB generator for each handpiece system above. The MAG RF generator is a portable reusable device that produces and delivers monopolar and bipolar RF energy at 460 kHz. It provides a pass-thru to an external sense and pace system (feature relates to the Pen devices). The MAG consists of several circuit boards, power supplies, a power entry module, a footswitch interface, and an LCD display with an integrated touchscreen. Like the ASU/ASB generator, the main function of the MAG is to deliver and control of voltage and current output to the selected handpiece. Upon reaching a predetermined threshold (voltage and/or current relationship or a preset time), the RF generator will provide visual and audible indications to signal the end of the ablation cycle and decrease the energy level until RF is stopped or the time limit is reached. A footswitch and a Start-Stop button on the touchscreen are included in the system to start and stop RF ablation. The output of the MAG generator is designed to be equivalent to the ASU/ASB generator when connected to each handpiece listed above.

IV. Intended Use/ Indications for Use

Isolator Linear Pen (MLP1)

The Isolator linear pen is a sterile, single use electrosurgery device intended to ablate cardiac tissue during cardiac surgery using radiofrequency (RF) energy when connected directly to the ASU/ASB or MAG 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.

Isolator Transpolar Pen (MAX1, MAX5)

The Isolator Transpolar Pen is a sterile, single use electrosurgery device intended to ablate cardiac tissue during cardiac surgery using radiofrequency (RF) energy.

The Isolator Transpolar 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.

Coolrail Linear Pen (MCR1)

The Coolrail® linear pen is a sterile, single use electrosurgery device intended to ablate cardiac tissue during cardiac surgery using radiofrequency (RF) energy.

Isolator Synergy Surgical Ablation System (EMR2/EML2)

The AtriCure Bipolar (Transpolar) System is intended to ablate cardiac tissue during surgery.

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

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

Isolator Synergy Access Clamp (EMT1)

The AtriCure Bipolar (Transpolar) System is intended to ablate cardiac tissue during surgery.

V. Proposed Change

The proposed change is to add an alternative radiofrequency (RF) generator, the Multifunctional Ablation Generator (MAG), for use with each of AtriCure's RF Pen and Clamp Handpieces. The MAG generator is equivalent to the ASU/ASB generator and has the same RF energy output when connected to each handpiece listed above.

VI. Comparison of Technological Characteristics:

- The single-use handpieces are not modified compared to the predicate systems;
- The alternate MAG generator has equivalent RF energy output as the ASU/ASB generator cleared for the predicate systems;
- The devices have the same intended use;
- No changes were made in operating principle, or performance specifications;
- The contraindications, warnings, and precautions remain the same;
- The results of the verification and validation testing:
    - demonstrated equivalence in performance
    - did not raise any safety concerns

VII. Performance Data

Verification and validation testing for the use of an alternative RF generator, MAG, were completed per AtriCure's Quality System to verify the device's conformance to appropriate design controls and specifications to demonstrate equivalence to the devices as previously cleared for use with the predicate ASU RF Generator.

Software verification and validation were completed for the MAG generator to assure that MAG features and functions operate correctly and are equivalent to the ASU/ASB generator.

Electrical safety and electromagnetic compatibility (EMC) testing were conducted, and the results demonstrated that the MAG RF performance is in accordance with the following standards:

Table 1: Electrical Standards

Standard	FDA Consensus #	Description
IEC 60601-1	19-4	*Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1-2	19-8	*Medical Electrical Equipment Part 1-2: General requirements for safety – Collateral Standard: Electromagnetic Compatibility – Requirements and tests*
IEC 60601-2-2	6-389	*Medical electrical equipment – Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories*

Environmental and transportation testing were conducted to assure that packaging is acceptable and that the MAG generator can withstand expected environmental conditions of transportation and use.

Bench testing was conducted to characterize and confirm that MAG load curves are equivalent to ASU/ASB load curves for each handpiece listed above.

System testing with each handpiece was completed including ex-vivo lesion equivalency testing to confirm that system performance with the MAG generator is equivalent to performance with the ASU/ASB generator.

Substantial Equivalence

AtriCure has conducted performance testing for each of the clamps and pens listed above with the MAG generator to establish equivalent system performance compared with use of the ASU/ASB generator. There are no changes to the handpiece designs or specifications and the system performance with the MAG generator was equivalent to performance with the ASU/ASB generator.

The following tables summarizes the specifications for each of the clamps and pens included in this bundled submission.

- Isolator Synergy Clamps EMR2 and EML2 Substantial Equivalence

Table 2: EMR2 and EML2 Technological Characteristics Comparison

#	Category	Feature/Item	Current - Isolator Synergy Clamps (EMR2 & EML2)	Proposed Isolator Synergy Clamps (EMR2 & EML2) with ASU/ASB or MAG	Equivalence Comparison
1.	General Information	**510(k) Reference**	K211311	K221358	N/A
2.		**Device Classification / Product Code**	Class II, 21 CFR § 878.4400 OCL	Class II, 21 CFR § 878.4400 OCL	Same
3.		**Intended Use**	The AtriCure Bipolar (Transpolar) System is intended to ablate cardiac tissue during surgery.	The AtriCure Bipolar (Transpolar) System is intended to ablate cardiac tissue during surgery.	Same
4.		**Accessory/ Positioning Guide**	Product Name: Glidepath Tape (GPT100, GPT200, GPT300)	Product Name: Glidepath Tape (GPT100, GPT200, GPT300)	Same
5.	Device Construction	**End-Effector Configuration**	Opposing, curved, insulated jaws with two electrodes running axially and medially on the inner surface of each jaw	Opposing, curved, insulated jaws with two electrodes running axially and medially on the inner surface of each jaw	Same
6.		**Jaw Tip**	Rounded proximal jaw tip and receptacle (attachment) tip on distal jaw for use with or without the Glidepath soft guide	Rounded proximal jaw tip and receptacle (attachment) tip on distal jaw for use with or without the Glidepath soft guide	Same
7.		**Number of Electrodes and location**	Two (2) electrode pairs (total four (4) electrodes) consisting of opposing linear electrodes located medially and axially on insulated inner surface of each opposing jaw.	Two (2) electrode pairs (total four (4) electrodes) consisting of opposing linear electrodes located medially and axially on insulated inner surface of each opposing jaw.	Same
8.		**Power Output**	28.5 W Max Based on proprietary algorithm which senses tissue impedance.	28.5 W Max Based on proprietary algorithm which senses tissue impedance.	Same
9.	Sterilization and Other	**Packaging**	PETG blister with Tyvek® lid	PETG blister with Tyvek® lid	Same
10.		**Sterilization**	Ethylene Oxide	Ethylene Oxide	Same
11.		**Sterility Assurance Level**	10^{-6} SAL	10^{-6} SAL	Same
12.		**Biocompatibility**	Meets requirements of ISO 10993	Meets requirements of ISO 10993	Same
13.	RF Generator	**Generator**	ASU / ASB	ASU / ASB OR MAG	Equivalent
14.		**Algorithm**	G	G	Same
15.		**RF Frequency and duration**	28.5 W for 40 sec.	28.5 W for 40 sec.	Same

- Isolator Synergy Access System EMT1 Substantial Equivalence

Table 3: EMT1 Technological Characteristics Comparison

#	Category	Feature	Current - Isolator Synergy Access System (EMT1)	Proposed – Isolator Synergy Access System (EMT1) with ASU/ASB or MAG	Equivalence Comparison
1.	General Information	**510K Reference**	K110117	K221358	N/A
2.		**Device Classification/ Product Code**	Class II, 21 CFR § 878.4400 OCL	Class II, 21 CFR § 878.4400 OCL	Same
3.		**Intended Use**	The AtriCure Bipolar (Transpolar) System is intended to ablate cardiac tissue during surgery.	The AtriCure Bipolar (Transpolar) System is intended to ablate f cardiac tissue during surgery.	Same
4.		**Accessory/Positioning Guide**	Product Name: Glidepath Tape (GPT100, GPT200, GPT300)	Product Name: Glidepath Tape (GPT100, GPT200, GPT300)	Same
5.	Device Construction	**End-Effector Configuration**	Parallel, opposing, convex curve left to right, insulated jaws with two electrodes running axially and medially on the inner surface of each jaw	Parallel, opposing, convex curve left to right, insulated jaws with two electrodes running axially and medially on the inner surface of each jaw	Same
6.		**Jaw Tip**	Rounded proximal jaw tip and receptacle (attachment) tip on distal jaw for use with or without the Glidepath soft guide	Rounded proximal jaw tip and receptacle (attachment) tip on distal jaw for use with or without the Glidepath soft guide	Same
7		**Number of Electrodes and location**	Four (4), two electrode pairs consisting of opposing linear electrodes located medially and axially on the insulated inner surface of each opposing jaw.	Four (4), two electrode pairs consisting of opposing linear electrodes located medially and axially on the insulated inner surface of each opposing jaw.	Same
8.		**Power Output**	28.5 W Max Based on proprietary algorithm which senses tissue impedance.	28.5 W Max Based on proprietary algorithm which senses tissue impedance.	Same
9.	Sterilization and Other	**Packaging**	PETG blister with Tyvek Lid	PETG blister with Tyvek Lid	Same
10.		**Sterilization**	Ethylene Oxide	Ethylene Oxide	Same

#	Category	Feature	Current - Isolator Synergy Access System (EMT1)	Proposed – Isolator Synergy Access System (EMT1) with ASU/ASB or MAG	Equivalence Comparison
11.		**Sterility Assurance Level**	10^{-6} SAL	10^{-6} SAL	Same
12.		**Biocompatibility**	Meets requirements of ISO 10993	Meets requirements of ISO 10993	Same
13.	**RF Generator**	**Generator**	ASU/ASB	ASU/ASB OR MAG	Equivalent
14.		**Algorithm**	G	G	Same
15.		**RF Frequency and duration**	28.5 W for 40 sec.	28.5 W for 40 sec.	Same

- EnCompass OLH/OSH Substantial Equivalence

Table 4: **OLH and OSH Technological Characteristics Comparison**

#	Category	Feature	Current - Isolator Synergy EnCompass Clamp (OLH/OSH)	Proposed – Isolator Synergy EnCompass Clamp (OLH/OSH) with ASU/ASB or MAG	Equivalence Comparison
1.	**General Information**	**510K Reference**	K210477	K221358	N/A
2.		**Device Classification/ Product Code**	Class II, 21 CFR § 878.4400 OCL	Class II, 21 CFR § 878.4400 OCL	Same
3.		**Intended 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
4.		**Accessory/ Positioning Guide**	Product Name: Glidepath Magnetic Tape (GMP100)	Product Name: Glidepath Magnetic Tape (GMP100)	Same
5.	**Device Construction**	**End-Effector Configuration**	Parallel 'Hex'-shaped jaws at closed position and hinges prior to reaching parallel closure. Two different lengths of jaws to allow for differing patient habitus.	Parallel 'Hex'-shaped jaws at closed position and hinges prior to reaching parallel closure. Two different lengths of jaws to allow for differing patient habitus.	Same

#	Category	Feature	Current - Isolator Synergy EnCompass Clamp (OLH/OSH)	Proposed – Isolator Synergy EnCompass Clamp (OLH/OSH) with ASU/ASB or MAG	Equivalence Comparison
8.		**Number of Electrodes and location**	Four (4), two electrode pairs consisting of opposing linear electrodes located medially and axially on the insulated inner surface of each opposing jaw.	Four (4), two electrode pairs consisting of opposing linear electrodes located medially and axially on the insulated inner surface of each opposing jaw.	Same
9.		**Power Output**	28.5 W Max Based on proprietary algorithm which senses tissue impedance.	28.5 W Max Based on proprietary algorithm which senses tissue impedance.	Same
10.	**Sterilization and Other**	**Packaging**	PETG blister with Tyvek Lid	PETG blister with Tyvek Lid	Same
11.		**Sterilization**	Ethylene Oxide	Ethylene Oxide	Same
12.		**Sterility Assurance Level**	10^{-6} SAL	10^{-6} SAL	Same
13.		**Biocompatibility**	Meets requirements of ISO 10993	Meets requirements of ISO 10993	Same
14.	**RF Generator**	**Generator**	ASU/ASB	ASU/ASB OR MAG	Equivalent
15.		**Algorithm**	G	G	Same
16.		**RF Frequency and duration**	28.5 W for 40 sec.	28.5 W for 40 sec.	Same

- Isolator Transpolar Pen MAX1/5 Substantial Equivalence

Table 5: MAX1 and MAX5 Technological Characteristics Comparison

#	Category	Feature	Current – Isolator Transpolar Pen (MAX1/5)	Proposed – Isolator Transpolar Pen (MAX1/5) with ASU/ASB or MAG	Equivalence Comparison
1.	**General Information**	**510K reference**	K192125	K221358	N/A
2.		**Device Classification / Product Code**	Class II, 21 CFR § 878.4400 OCL	Class II, 21 CFR § 878.4400 OCL	Same
3.		**Intended Use**	The Isolator Transpolar Pen is a sterile, single use electrosurgery	The Isolator Transpolar Pen is a sterile, single use electrosurgery	Equivalent – Adjusted

			device intended to ablate cardiac tissue during cardiac surgery using radiofrequency (RF) energy when connected directly to the ASU or to the ASU Source Switch in Ablation mode. When the Pen is connected to the ASU Source Switch in Auxiliary mode, it may be used for temporary cardiac sensing, recording, stimulation, and temporary pacing during the evaluation of cardiac arrhythmias.	device intended to ablate cardiac tissue during cardiac surgery using radiofrequency (RF) energy. The Isolator Transpolar 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.	language to align with AtriCure's other RF devices.
4.		**Contraindication**	The device is not intended for contraceptive tubal coagulation (permanent female sterilization). Do not ablate directly on cardiac valves.	The device is not intended for contraceptive tubal coagulation (permanent female sterilization). Do not ablate directly on cardiac valves.	Same
5.	**Device Construction**	**Ablating Element Length**	8mm	8mm	Same
8.		**Electrode Number**	2	2	Same
9.	**Sterilization and Other**	**Packaging**	PETG blister with Tyvek Lid	PETG blister with Tyvek Lid	Same
10.		**Sterilization**	Ethylene Oxide	Ethylene Oxide	Same
11.		**Sterility Assurance Level**	10^{-6} SAL	10^{-6} SAL	Same
12.		**Biocompatibility**	Meets requirements of ISO 10993	Meets requirements of ISO 10993	Same
13.	**RF Generator**	**Generator**	ASU/ASB	ASU/ASB OR MAG	Equivalent
14.		**Algorithm**	B	B	Same
15.		**RF Frequency and duration**	15W for 40s	15W for 40s	Same

- Multifunctional Linear Pen MLP1 Substantial Equivalence

Table 6: MLP1 Technological Characteristics Comparison

#	Category	Feature	Current – Isolator Linear Pen (MLP1)	Proposed – Isolator Linear Pen (MLP1) with ASU/ASB or MAG	Equivalence Comparison
1.	General Information	**510K reference**	K192125	K221358	N/A
2.		**Device Classification/ Product Code**	Class II, 21 CFR § 878.4400 OCL	Class II, 21 CFR § 878.4400 OCL	Same
3.		**Intended Use**	The Isolator linear pen is a sterile, single use electrosurgery device intended to ablate cardiac tissue during cardiac surgery using radiofrequency (RF) energy when connected directly to the ASU or to the ASU Source Switch 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.	The Isolator linear pen is a sterile, single use electrosurgery device intended to ablate cardiac tissue during cardiac surgery using radiofrequency (RF) energy to the ASU/ASB or MAG 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.	Equivalent – Adjusted language to align with AtriCure's other RF devices.
4.		**Contraindication**	The device is not intended for contraceptive tubal coagulation (permanent female sterilization). Do not ablate directly on cardiac valves.	The device is not intended for contraceptive tubal coagulation (permanent female sterilization). Do not ablate directly on cardiac valves.	Same
5.					
6.	Device Construction	**Ablating Element Length**	20 mm	20 mm	Same
10.		**Electrode Number**	4 total: 2 ablation and 2 for pacing / sensing	4 total: 2 ablation and 2 for pacing / sensing	Same
11.	Sterilization and Other	**Packaging**	Tyvek Pouch with HDPE insert card	Tyvek Pouch with HDPE insert card	Same
12.		**Sterilization**	Ethylene Oxide	Ethylene Oxide	Same
13.		**Sterility Assurance Level**	10^{-6} SAL	10^{-6} SAL	Same
14.		**Biocompatibility**	Meets requirements of ISO 10993	Meets requirements of ISO 10993	Same

#	Category	Feature	Current – Isolator Linear Pen (MLP1)	Proposed – Isolator Linear Pen (MLP1) with ASU/ASB or MAG	Equivalence Comparison
15.	RF Generator	**Generator**	ASU/ASB	ASU/ASB OR MAG	Equivalent
16.		**Algorithm**	C	C	Same
17.		**RF Frequency and duration**	20W for 40s	20W for 40s	Same

- Coolrail Linear Pen MCR1 Substantial Equivalence

Table 7: MCR1 Technological Characteristics Comparison

#	Category	Feature	Current – Coolrail Linear Pen (MCR1)	Proposed – Coolrail Linear Pen (MCR1) with ASU/ASB or MAG	Equivalence Comparison
1.	General Information	**510K reference**	K190587	K221358	N/A
2.		**Device Classification/ Product Code**	Class II, 21 CFR § 878.4400 OCL	Class II, 21 CFR § 878.4400 OCL	Same
3.		**Intended Use**	The Coolrail® Linear pen is a sterile, single use electrosurgery device intended to ablate cardiac tissue during cardiac surgery using radiofrequency (RF) energy.	The Coolrail® linear pen is a sterile, single use electrosurgery device intended to ablate cardiac tissue during cardiac surgery using radiofrequency (RF) energy.	Same
4.		**Contraindication**	The device is not intended for contraceptive tubal coagulation (permanent female sterilization).	The device is not intended for contraceptive tubal coagulation (permanent female sterilization).	Same
5.	Device Construction	**Ablating Element Length**	30 mm	30 mm	Same
11.		**RF and Pump control module**	Circuit board controlled.	Circuit board controlled.	Same
21.	Sterilization and Other	**Packaging**	PETG blister with Tyvek Lid	PETG blister with Tyvek Lid	Same
22.		**Sterilization**	Ethylene Oxide	Ethylene Oxide	Same
23.		**Sterility Assurance Level**	10^{-6} SAL	10^{-6} SAL	Same
24.		**Biocompatibility**	Meets requirements of ISO 10993	Meets requirements of ISO 10993	Same
25.	RF Generator	**Generator**	ASU/ASB	ASU/ASB OR MAG	Equivalent
26.		**Algorithm**	L	L	Same
27.		**RF Frequency and duration**	30W for 40s	30W for 40s	Same

VIII. Conclusions

AtriCure has demonstrated that each of AtriCure's RF Handpieces, when connected to the Multifunctional Ablation Generator (MAG) is substantially equivalent in performance, safety, and intended use to AtriCure's previously cleared RF Handpieces 510(k)s with the ASU/ASB Generator.