February 13, 2024

AtriCure, Inc.
Jenifer Ulrikson
Regulatory Affairs Specialist
7555 Innovation Way
Mason, Ohio 45040

Re: K233959
Trade/Device Name: EPi-Ease™ Epicardial Access Device (EAS)
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter introducer
Regulatory Class: Class II
Product Code: DYB
Dated: December 14, 2023
Received: December 15, 2023

Dear Jenifer Ulrikson:

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.

510(k) Number *(if known)*
K233959

Device Name
EPi-Ease™ Epicardial Access System (EAS)

Indications for Use *(Describe)*
The EPi-Ease™ Epicardial Access System is intended to access the epicardial surface of the heart via a subxiphoid approach.

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.

K233959

510(k) Summary

Applicant Information

Manufacturer: AtriCure, Inc.
7555 Innovation Way
Mason Ohio 45040

Contact Person: Jeni Ulrikson
Senior Regulatory Affairs
Specialist Cell: 763-691-3904

Device Information

Proprietary Name: EPi-Ease™ Epicardial Access System (EAS)

Common Name: EPi-Ease

Classification: Introducer, Catheter
Regulatory Class: Class II; per 21 CFR 870.1340
Product Code: DYB
Classification Panel: Cardiovascular

Predicate Device: Agilis PF Introducer System
(K111943, September 29, 2011)

Device Description

EPi-Ease is composed of a radiopaque blunt dissection distal tip, a distal suction port designed to draw pericardial tissue into the device, a hollow 22-gauge Tuohy needle that enables puncture of the pericardium internal to the device, and a lumen to allow for insertion of an endoscope to provide direct visualization during blunt dissection, needle puncture, and guidewire delivery. The distal suction port connects to the device handle and terminates in a standard luer connection. The needle connects to the handle and terminates in a needle actuator, which enables extension, retraction, and rotation of the encased needle a limited distance within the distal tip and provides a port for insertion of a commercially available guidewire. After puncture, the device allows passage of a standard, commercially available .014” guidewire. An additional flushing port is available using the 3-way stopcock.

Intended Use / Indications for Use

The EPi-Ease™ Epicardial Access System is intended to access the epicardial surface of the heart via a subxiphoid approach.

Comparison of Technological Characteristics

- The devices include an equivalent intended use, and;
- No changes were made in operating principle, and;
- The results of the verification and validation testing:
  - Demonstrated equivalency in performance
  - Did not raise any new issues of safety

	Feature	**Predicate:** **Agilis Epicardial Access System**	**Proposed:** **AtriCure EPi-Ease System**
1	Access	Sub-xiphoid	Sub-xiphoid
2	Needle size and Device Profile	17 ga. Tuohy Needle 18 Fr. Device Profile	22 ga. Tuohy Needle 13 Fr. Device Profile
3	Visualization	Fluoroscopy required No endoscopic visualization	Fluoroscopy required Endoscopic visualization
4	Indication for Use	The Epicardial Access System is intended to access the epicardial surface of the heart via a subxiphoid approach to facilitate electrophysiology studies	The EPi-Ease™ Epicardial Access System is intended to access the epicardial surface of the heart via subxiphoid approach
5	Vacuum	N/A	Vacuum-enabled retraction
6	Radiopaque marker	Yes—distal tip	Yes—distal tip
7	Operating Principles	Advancement through adipose tissue to reach pericardial sac, needle punctures pericardial sac, guidewire advances through needle into pericardial sac, introducer advances over guidewire and pre- dilates pericardial sac, sheath advances over guidewire into pericardial sac to access epicardial surface of the heart.	Equivalent. EPi-Ease adds direct visualization, vacuum, and needle advancement limits to mitigate risks associated with the predicate

Performance Data

The following bench testing was conducted for design and performance elements deemed appropriate to demonstrate substantial equivalence to the previously cleared Agilis Introducer. The EPi-Ease device met the predetermined acceptance criteria ensuring substantial equivalence to the predicate. No new safety or effectiveness issues were raised during testing.

Non-clinical Bench Testing:

Test Description	Results
Mechanical Testing: Endoscope testing, guidewire compatibility, structural integrity	PASS
Biocompatibility Testing per ISO 10993-1	PASS
Shelf-Life Testing ASTM F1980-16	PASS
Transit Testing per ISTA 3A	PASS
Sterilization per ISO 11137	PASS
Synthetic Model (CADet) testing	PASS

Conclusion

AtriCure has demonstrated that the EPi-Ease Epicardial Access Device is substantially equivalent in fundamental design, technology, function, device materials, packaging, sterilization, operating principal, and intended use/ indication for use to the predicate device, the Agilis PF Introducer System.