April 24, 2025

CIRCA Scientific, Inc.
Alice Ouyang
Regulatory Affairs Manager
14 Inverness Drive East, Suite H-136
Englewood, Colorado 80112

Re: K243954
Trade/Device Name: PeriCross™ Epicardial Access Kit
Regulation Number: 21 CFR 870.1340
Regulation Name: Introducer, Catheter
Regulatory Class: Class II
Product Code: DYB
Dated: March 25, 2025
Received: March 25, 2025

Dear Alice Ouyang:

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

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)*
K243954

Device Name
PeriCross™ Epicardial Access Kit

Indications for Use *(Describe)*
The PeriCross™ Epicardial Access Kit is intended to access the epicardial surface of the heart via a subxiphoid approach to facilitate electrophysiology studies in adult patients.

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.

510(k) SUMMARY

1 Submitter

CIRCA Scientific Inc.
14 Inverness Drive East, Suite H-136
Englewood, CO 80112
Phone: (303) 951-8767
Contact: Alice Ouyang
Date Prepared: 21 April 2025

2 Device Information

Trade Name/Proprietary:	PeriCross™ Epicardial Access Kit
Common or Usual Name:	Catheter Introducer
Classification Name:	Introducer, Catheter
Regulatory Class:	II
Product Code(s):	DYB
Regulation Number:	21 CFR 870.1340
Predicate Device:	Primary: St Jude Medical Agilis™ PF Introducer System and accessories, K111943
	Secondary: Merit MAK (Mini Access Kit), K031691
Reference Device:	Epi-Ease Cardiac Access Device, K233959

3 Indication for Use

The PeriCross™ Epicardial Access Kit is intended to access the epicardial surface of the heart via a subxiphoid approach to facilitate electrophysiology studies in adult patients.

4 Device Description

The PeriCross™ Epicardial Access Kit is designed to provide safe and reliable access to the epicardium. The kit is supplied sterile and is designed to deliver a .018” guidewire to the pericardial space.

The PeriCross™ Epicardial Access Kit consists of the following components:

- One (1) PeriCross™ Tunneler Assembly
- One (1) PeriCross™ Access Device
- One (1) Guidewire – 0.018” OD × 80cm Long
- One (1) Coaxial Introducer – 5F × 18cm

The PeriCross™ Tunneler assembly consists of a cannula and a removable blunt obturator that, together, create an atraumatic assembly, which is utilized to gain access to the pericardium via the subxiphoid approach. When the tip of the PeriCross™ Tunneler Assembly reaches the pericardial surface, the obturator is removed, leaving a path to the pericardial surface through the open cannula. The PeriCross™ Access Device is inserted into the cannula and secured via a snap connection. The PeriCross™ Access Device incorporates a thumb slide that deploys tines to engage and retract the pericardium away from the surface of the epicardium. The space created allows for the deployment of an integrated 21ga needle to puncture the pericardium in a location away from the heart. The PeriCross™ Access Device prevents inadvertent deployment of the needle and retraction of the tines via an interlock mechanism. A .018" guidewire can then be deployed through the PeriCross™ Access Device. A 5F x 18cm coaxial introducer is provided to allow for subsequent dilation and guidewire exchange to a .032" guidewire.

5 Comparison to Predicate Device

5.1 Comparison to Primary Predicate

Attribute	**Predicate** **St Jude Medical Agilis™ PF Introducer System and Accessories (K111943)**	**Subject Device** **CIRCA Scientific PeriCross Epicardial Access Kit**
Class	II	II
Product Code	DYB	DYB
Regulation (FDA)	870.1340	870.1340
Intended Use / Indications for Use	The Agilis™ PF Introducer System is intended to access the epicardial surface of the heart via a subxiphoid approach to facilitate electrophysiology studies.	The PeriCross™ Epicardial Access Kit is intended to access the epicardial surface of the heart via a subxiphoid approach to facilitate electrophysiology studies in adult patients.
Where Used	Subxiphoid approach to the epicardial surface of the heart.	Subxiphoid approach to the epicardial surface of the heart.
Included Components	• 17 Ga Touhy Needle • Obturator • Guidewire • Deflectable Introducer with dilator	• PeriCross Tunneler with Obturator • PeriCross Access Device • Guidewire • Coaxial Introducer with dilator

Attribute	**Predicate** **St Jude Medical Agilis™ PF Introducer System and Accessories (K111943)**	**Subject Device** **CIRCA Scientific PeriCross Epicardial Access Kit**
Principals of Operation	Access to the pericardial space is achieved through a subxiphoid incision by advancing a Touhy needle above the diaphragm towards the heart and puncturing the pericardium. Centimeter markings on the needle aid in monitoring its progress, and contrast injection confirms correct placement. Afterward, a guidewire is introduced, the needle is replaced with an introducer and dilator, and the dilator is removed to allow for the placement of an obturator.	Access to the pericardial space is achieved via a subxiphoid incision using the PeriCross Tunneler with an obturator, which is removed to insert the PeriCross Access Device with an integrated needle. Contrast is injected through the needle to visualize the cardiac silhouette, and tines are deployed to capture and retract the pericardium from the heart's epicardial surface. The needle punctures the pericardium, and a guidewire is introduced to confirm access. The PeriCross Access Device is then removed, and an introducer with a dilator is inserted over the guidewire, allowing for the exchange to a larger guidewire for the continuation of the procedure.
Component Dimension – Needle	17 Ga Needle (0.056”, 1.4 mm) Length: 11.4 cm	21 Ga Needle (0.032”, 0.8 mm) Effective length: 13.2 cm.
Component Dimension – Guidewire	OD: 0.032” Length: 100 cm	OD: 0.018” Length: 80 cm
Component Dimension – Introducer	ID: 13 F Length: 40 cm	OD: 5 F Length: 18 cm
Materials	Plastic and Stainless Steel	Plastic and Stainless Steel
Sterility	Ethylene oxide	Ethylene oxide

The subject device includes a feature to retract the pericardial tissue prior to puncture; the predicate device does not have this feature. However, a reference device, Epi-Ease Cardiac Access Device (K233959), has the same intended use as the subject device and is also designed to retract the pericardial tissue prior to puncture. This reference device demonstrates that the testing methods used to demonstrate substantial equivalence between the subject and predicate devices are acceptable, because the same non-clinical bench testing methods were used for both the subject device and reference device. The reference device was not clinically tested.

5.2 Comparison to Secondary Predicate (for Introducer only)

Attribute	Secondary Predicate Merit MAK (Mini Access Kit) (K031691)	Subject Device CIRCA Scientific PeriCross Epicardial Access Kit - Introducer
Intended Use / Indications for Use	The Merit® MAK (Mini Access Kit) is intended for percutaneous placement of a 0.035" (0.89mm) or 0.038" (0.97mm) guide wire into the vascular system.	The PeriCross™ Epicardial Access Kit is intended to access the epicardial surface of the heart via a subxiphoid approach to facilitate electrophysiology studies in adult patients.
Outer Diameter	5F	5F
Length	15 cm	18 cm
Materials	Plastic and Stainless Steel	Plastic and Stainless Steel
Sterility	Ethylene oxide	Ethylene oxide

The predicates and subject device have an equivalent intended use / indication for use.

The differences in operation principle and dimensions of components do not raise different questions of safety or performance when compared to the predicates. The results of performance testing demonstrate that the subject device is as safe and effective as the predicate devices.

The PeriCross™ Epicardial Access Kit is substantially equivalent to the predicate devices based on comparisons of the intended use / indication for use, principles of operation, and technological characteristics.

6 Summary of Non-Clinical Performance Testing

The following non-clinical performance testing was performed to demonstrate the device meets its design specification and is as safe and effective as the predicate device.

Test Description	Results
Mechanical Testing: Dimension measurements, tensile, stiffness, breakage, corrosion, insertion, puncture.	Pass
Biocompatibility Testing per ISO 10993-1	Pass
Shelf-Life Testing per ASTM F1980	Pass
Transit Testing per ISTA 3A	Pass
Sterilization Testing per ISO 11135	Pass

7 Summary of Clinical Testing

A prospective, non-randomized, single-arm clinical study was conducted to compare the epicardial access success of the subject device with the historical control of a Touhy needle. The

study was conducted per ISO 14155. A total of 39 adult patients met the inclusion criteria and were included in the analysis. The primary efficacy endpoint of achieving guidewire access to the pericardial space using the PeriCross Epicardial Access Kit, confirmed by standard X-ray technique, was achieved in all subjects. There were two non-serious cardiac perforations (≤ 80 mL of bleeding) and one serious cardiac perforation (≥ 80 mL of bleeding), with no surgery required for closure. The study demonstrated that the PeriCross Epicardial Access Kit can safely achieve epicardial access by providing guidewire access to the pericardial space.

8 Conclusions

The subject device has the same intended use / indication for use as the predicate devices and the reference device. The subject device also has similar principles of operation and technological characteristics as the predicates and the reference device. Results from performance testing (including bench and clinical) demonstrated that, despite differences in technological characteristics, the subject device does not raise different questions of safety and effectiveness. Therefore, the subject device, PeriCross™ Epicardial Access Kit, is considered substantially equivalent to the predicates, Agilis™ PF Introducer System and Accessories (K111943) and Merit MAK (Mini Access Kit) (K031691), with the reference device considered.