January 31, 2024

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

Re: K240004
Trade/Device Name: CardioCurve™ Steerable Sheath
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: December 30, 2023
Received: January 2, 2024

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.

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K240004

Device Name
CardioCurve™ Steerable Sheath

Indications for Use *(Describe)*
The CIRCA Scientific CardioCurve™ Steerable Sheath is indicated when introducing various cardiovascular devices to the epicardial or endocardial surfaces of the heart, including the left side of the heart through the interatrial septum.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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: December 28, 2023

2 Device Information

Name of Device:	CardioCurve™ Steerable Sheath
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:	CardioCurve™ Steerable Sheath, K210185

3 Device Description

The CardioCurve™ Steerable Sheath from CIRCA Scientific is an 8.5 Fr sterile, single-use catheter introducer used for the introduction, withdrawal, and exchange of guidewires and catheters while minimizing blood loss. It is available in lengths of 40cm, 61cm, 71cm, or 82cm. The introducer is packaged with a custom dilator and a 180 cm, 0.032”, super stiff, marketed cleared guidewire (K935170). A side port with a 3-way stopcock allows air or blood aspiration, fluid infusion, blood sampling, and pressure monitoring. A handle equipped with two linked rotating dials is used to deflect the tip clockwise and counterclockwise 180°. The steerable sheath features distal vent holes to facilitate aspiration and minimize cavitation, a radiopaque tip marker to improve fluoroscopic visualization, and a lubricious coating on the outer surface.

The CardioCurve™ Steerable Sheath shaft is made from Pebax and Nylon. The shaft includes a radiopaque tip marker for visibility under fluoroscopy and is braided, except for the distal tip, for kink resistance; the handle is made of ABS. The dilator is made of HDPE that is barium loaded for visibility under fluoroscopy.

The CardioCurve™ dilator can be used with a curved transseptal Abbott BRK™ type needle with stylet if indicated on the package label.

This Special 510(k) is submitted to support the changes made to the predicate device: the Tuohy Borst adapter in the CardioCurve Steerable Sheath is replaced with a cap; as a result of this

change, the dilator shaft usable length is shortened, and the Instruction for Use (IFU) is updated. Verification testing has been conducted to support that the subject device meets the design specifications and is substantially equivalent to the predicate device.

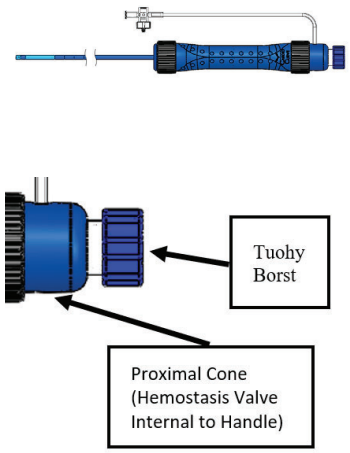
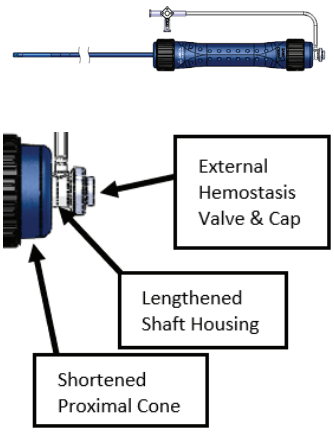
4 Indication for Use

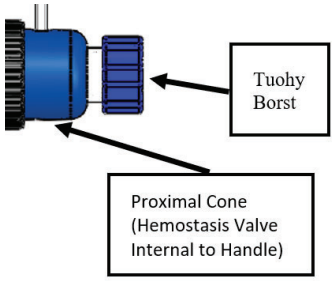
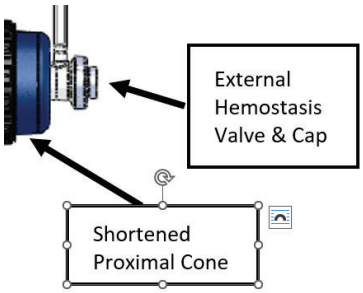
The CIRCA Scientific CardioCurve™ Steerable Sheath is indicated when introducing various cardiovascular devices to the epicardial or endocardial surfaces of the heart, including the left side of the heart through the interatrial septum.

5 Comparison of Technological Characteristics with the Predicate Device

Attribute	CardioCurve Steerable Sheath – Predicate (K210185)	CardioCurve Steerable Sheath – Subject Device	Discussion
Class	II	II	Identical
Product Code	DYB	DYB	Identical
Regulation (FDA)	870.1340	870.1340	Identical
Intended Use	To provide access to the heart for use of cardiovascular devices.	To provide access to the heart for use of cardiovascular devices.	Identical
Indications for Use	The Talon Surgical CardioCurve™ Steerable Sheath is indicated when introducing various cardiovascular devices to the epicardial or endocardial surfaces of the heart, including the left side of the heart through the interatrial septum.	The CIRCA Scientific CardioCurve™ Steerable Sheath is indicated when introducing various cardiovascular devices to the epicardial or endocardial surfaces of the heart, including the left side of the heart through the interatrial septum.	Identical (Company name, Talon Surgical, was replaced by CIRCA Scientific)
Where Used	Endocardial and Epicardial indications	Endocardial and Epicardial indications	Identical

Attribute	CardioCurve Steerable Sheath – Predicate (K210185)	CardioCurve Steerable Sheath – Subject Device	Discussion
Principles of Operation	Access is obtained, the 0.032" guidewire is inserted and positioned. The CardioCurve Steerable Sheath with dilator is inserted over the guidewire into the desired position. The access needle and dilator are removed. The sheath tip is deflected by turning the actuators to obtain the desired position. Treatment devices are positioned through the sheath. The tip position can be manipulated using the actuators. Rotating actuators deflect the shaft.	Access is obtained, the 0.032" guidewire is inserted and positioned. The CardioCurve Steerable Sheath with dilator is inserted over the guidewire into the desired position. The access needle and dilator are removed. The sheath tip is deflected by turning the actuators to obtain the desired position. Treatment devices are positioned through the sheath. The tip position can be manipulated using the actuators. Rotating actuators deflect the shaft.	Identical
Target Population	Patients whose doctors need minimally invasive access to the heart.	Patients whose doctors need minimally invasive access to the heart.	Identical
Placement	Epicardial, endocardial, and intravascular sites	Epicardial, endocardial, and intravascular sites	Identical
Size	8.5F (2.9mm)	8.5F (2.9mm)	Identical
Curl	Bi-directional 180°, small (17mm), medium (22.5 mm), and large (50mm) curl. Deflectable from 2 linked locations on the handle.	Bi-directional 180°, small (17mm), medium (22.5 mm), and large (50mm) curl. Deflectable from 2 linked locations on the handle.	Identical
Steerable Sheath Usable Length	40, 61, 71 and 82 cm	40, 61, 71 and 82 cm	Identical

Attribute	CardioCurve Steerable Sheath – Predicate (K210185)	CardioCurve Steerable Sheath – Subject Device	Discussion
Steerable Sheath Shape			**Modification Design (Shape) to steerable sheath handle (Tuohy Borst adapter replacement by cap and external hemostasis valve due to shortened proximal cone and lengthened shaft housing). Changes to steerable sheath shape do not raise new or different questions of safety and effectiveness.**
Dilator OD	9F (3mm)	9F (3mm)	Identical
Dilator Useable Length	61.7, 82.7, 92.7, and 103.7 cm	60.95, 81.95, 91.95, and 102.95 cm	**Modification in Design (Length) to match modification to steerable sheath shape. Changes to the lengths do not raise new or different questions of safety or effectiveness.**
Design	Sideport with 3-way stopcock	Sideport with 3-way stopcock	Identical
	Distal holes in the shaft	Distal holes in the shaft	Identical
	Radiopaque filled sheath	Radiopaque filled sheath	Identical
	Tuohy Borst adapter. Tuohy Borst adapter mates with dilator. Tuohy Borst Material: Makrolon 2458-550115 Polycarbonate	Tuohy Borst adapter not provided. Replaced by Cap. Cap mates with dilator. Cap Material: Makrolon 2458-550115 Polycarbonate	**Modification in Design (Shape) to steerable sheath handle. Tuohy Borst adapter removal does not raise new or different questions of safety or effectiveness.**

Attribute	CardioCurve Steerable Sheath – Predicate (K210185)	CardioCurve Steerable Sheath – Subject Device	Discussion
	Transparent hemostasis valve internal to steerable sheath handle. 	Transparent hemostasis valve external to steerable sheath handle. 	**Modification in Design (Shape) to steerable sheath handle (hemostasis valve). Changes to steerable sheath shape do not raise new or different questions of safety and effectiveness.**
	Proximal shaft braided	Proximal shaft braided	Identical
	Kink resistant	Kink resistant	Identical
Materials	Polymer shaft with Stainless Steel braid reinforcement and deflection wires.	Polymer shaft with Stainless Steel braid reinforcement and deflection wires.	Identical
Guidewire Compatibility	up to 0.032”	up to 0.032”	Identical
Features	• Atraumatic tip • Braided shaft for pushability / torqueability • Steerable Handle from 2 locations on the handle	• Atraumatic tip • Braided shaft for pushability / torqueability • Steerable Handle from 2 locationss on the handle	Identical
Sterility	100% Ethylene Oxide	100% Ethylene Oxide	Identical

The subject and predicate devices have the same intended use, indications for use, principles of operation, and target patient population.

The subject device differs from the predicate as follows:

1. Design:
    - Change in steerable sheath shape due to external hemostasis valve and removal of Tuohy Borst adapter.
        - Change in dilator length due to change in steerable sheath shape.
2. Labeling
    - Modification to Instructions for Use (IFU) to remove optional steps related to using the Tuohy Borst adapter due to removing the Tuohy Borst adapter.
    - Modification to IFU to add verbiage about visually inspecting for air bubbles inside the clear hemostatic valve housing.

The changes made to the predicate device do not raise any significant questions of safety or effectiveness. The subject device is substantially equivalent to the predicate device with regard to intended use, indications for use, and principles of operation.

6 Summary of Performance Testing

A failure modes and effects analysis (FMEA) of the subject device was conducted in accordance with an internal protocol based on *ISO 14971, Medical Devices – Risk Management for Medical Devices,* to ensure that the differences posed by the subject design were acceptable and that no new questions of safety and effectiveness were raised. Design verification tests were performed to demonstrate that the subject device, CIRCA Scientific CardioCurve Steerable Sheath, met predetermined performance specifications and to ensure that there were no significantly modified risks associated with the changes to the predicate design. Testing performed demonstrated that the subject device met critical design specifications as well as performance attributes for its intended use. The methods and acceptance criteria were the same or equivalent to the predicate device and are relevant to the changes under review. The testing identified in the list below was based on well-established test methods and requirements.

- Packaging Inspection
- Sheath Surface Visual Inspection
- Dilator Effective Length
- Dilator Extension from Sheath
- Sheath Deflection Fatigue and Wear
- Sheath Liner, Deflection Portion, and Coating Integrity
- Sideport Tube Infusion / Aspiration
- Sheath Fluid Leak Test – Hemostasis valve
- Sheath Fluid Leak Test – Fluid Path
- Air Aspiration Leak Test
- Sideport Tube to Shaft Housing Connection
- Dilator Hub to Cap Connection Strength
- Sheath Shaft to Handle/Hub Strength

7 Conclusions

The subject device has the same intended use, indication for use, and principles of operation as the predicate device. Results from verification testing demonstrated that the different technological characteristics did not raise different questions of safety and effectiveness. Therefore, the subject device, CIRCA Scientific CardioCurve™ Steerable Sheath, is considered substantially equivalent to the predicate, CardioCurve™ Steerable Sheath (K210185).