May 1, 2025

Circa Scientific, Inc.
% Jennifer Willner
President
JW Regulatory Consulting, LLC
406 Wacouta St, Suite 417
St. Paul, Minnesota 55101

Re: K251007
Trade/Device Name: CrossWise RF Transseptal Access System (Models: CW-1085S, CW-1085A, CW-1012W, CW-1012C, CW-1085C, CW-1085V, CW-1013F)
Regulation Number: 21 CFR 870.5175
Regulation Name: Septostomy Catheter
Regulatory Class: Class II
Product Code: DXF
Dated: April 1, 2025
Received: April 1, 2025

Dear Jennifer Willner:

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,

Katherine N. Trivedi
-S

Katherine Trivedi
Assistant Director
DHT2B: Division of Circulatory Support,
Structural, and Vascular Devices
OHT2: 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)*
K251007

Device Name
CrossWise RF Transseptal Access System
(Models: CW-1085S, CW-1085A, CW-1012W, CW-1012C, CW-1085C, CW-1085V, CW-1013F)

Indications for Use *(Describe)*
The CrossWise™ RF Transseptal Cannula and accessories are used to create an atrial septal defect in the heart. Secondary indications include infusing solutions including heparinized saline and mixtures of 50% contrast media and 50% saline.

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.

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CIRCA SCIENTIFIC

510(K) SUMMARY

510(k) Number: K251007

Date Prepared: March 31, 2025

Table 1: Submitter Information

Manufacturer: Circa Scientific, Inc. 14 Inverness Dr E, Suite H-136 Englewood, CO 80112 US FDA ERN: 3009437315	Manufacturer's Contact Person: Jennifer Willner, President JW Regulatory Consulting LLC Phone: (612) 240 - 8904 Email: Jennifer@JWRegulatoryConsulting.com

Table 2: Device Information

Trade Name	CrossWise™ RF Transseptal Access System
Common Name	Transseptal Access System
Classification Name	Catheter, Septostomy
Regulation	21CFR 870.5175
Product Code	DXF
Regulatory Classification:	Class II
Device Panel:	Cardiovascular

The Circa Scientific CrossWise RF Transseptal Access System line extensions are substantially equivalent to the previously cleared predicate CrossWise RF Transseptal Access System (**Table 3**).

Table 3: Predicate Devices

Predicate Device	Manufacturer	FDA 510(k)
CrossWise RF Transseptal Access System	Circa Scientific, Inc.	K241414

Device Description

The CrossWise RF Transseptal Access System is used to puncture the Fossa Ovalis (FO) to establish transcatheter access from the right atrium to the left atrium. Monopolar radiofrequency (RF) energy is delivered between the CrossWise focal force electrode and a patient return electrode. The unique design of the focal force electrode minimizes trauma to cardiac tissue unless RF energy is applied. A colored sleeve is provided on the CrossWise RF Transseptal Cannula handle to indicate to the user when the tip of the catheter is still within the dilator.

The CrossWise RF Transseptal Cannula is supplied with a compatible dilator and a Super Stiff 0.032" PTFE-Coated Fixed Core J-Tip guidewire for vascular introduction using an over-the-wire technique. The RF Transseptal Cannula is connected to a ValleyLabs Force2 Electrosurgical Generator (Medtronic, Inc) via the CrossWise Multi-Use RF Adapter Cable (packaged separately – Model CW-1001) and a commercially available Electrosurgical Pencil.

The CrossWise RF Transseptal Cannula is designed to facilitate injection of heparinized saline and/or contrast solution. The dimensions for the CrossWise RF Transseptal Cannula can be found on the device label. The CrossWise RF Transseptal Access System offers multiple configurations compatible with various commercially available guide sheaths (**Table 4**). All configurations require use of a CrossWise Multi-Use RF Adapter Cable (Model CW-1001) which is packaged separately.

Table 4: Compatible Introducer Sets

CrossWise RF Transseptal Access System		**Compatible Commercial Introducer Set**	
Description	**REF**	**Description**	**REF**
CrossWise 8.5Fr, 71cm C1 Swartz	CW-1085S	Swartz Braided Transseptal Guiding Introducer 8.5Fr, 63cm, SL0 and SL1 [St Jude Medical / Abbott]	407451 407453 407455
CrossWise 8.5Fr, 97cm C1 Agilis	CW-1085A	Agilis NxT Steerable Introducer 8.5Fr, 71cm, Small, Medium, Large Curl [St Jude Medical / Abbott]	408309 G408320 408310 G408321 G408324
CrossWise 12Fr, 88cm C1 Watchman	CW-1012W	Watchman [Boston Scientific]	M635TU70010 M635TU70020 M635TU70040 M635TU80010 M635TU80020 M635TU90050
CrossWise 12Fr, 88cm C1 FlexCath	CW-1012C	FlexCath Advance Steerable Sheath 12F [Medtronic]	4FC12
CrossWise 8.5Fr, 97cm C1 CardioCurve	CW-1085C*	CardioCurve [Circa Scientific]	CC-1071S CC-1071M CC-1071L
CrossWise 8.5Fr, 97cm C1 Vizigo	CW-1085V*	Vizigo [Biosense Webster]	D138501 D138502 D138503
CrossWise 13Fr, 97cm C1 Faradrive	CW-1013F*	Faradrive [Boston Scientific]	M004PF21M402

*These are the CrossWise line extension Models subject to this Special 510(k) application

Indications for Use

The CrossWise™ RF Transseptal Cannula and accessories are used to create an atrial septal defect in the heart. Secondary indications include infusing solutions including heparinized saline and mixtures of 50% contrast media and 50% saline.

Comparison of Technological Characteristics with the Predicate and Reference Device

The purpose of this submission is the addition of three new CrossWise RF Transseptal Access System line extensions: Models CW-1085C, CW-1085V, and CW-1013F. The only device affected by this change is the transseptal dilator component of the CrossWise system and only the proximal luer hub is modified. The material composition of the dilator, along with the

extruded shaft and distal tip design remain unchanged and are identical to the Predicate Device. The proximal luer hub has minor dimensional changes to accommodate proper connection with other commercial introducer sheaths: CardioCurve, Vizigo and Faradrive (**Table 4**).

These differences do not raise new questions regarding safety or effectiveness and do not impact the intended use of the device.

There is no change to the packaging of the CrossWise RF Transseptal Access System as a result of the line extensions. Labeling has been updated to include reference to the new model numbers.

Table 5: Substantial Equivalence Comparison Table

Feature	Subject Device	Predicate Device 1 (K241414)	Analysis of Differences
Product Name	CrossWise RF Transseptal Access System	CrossWise RF Transseptal Access System	Identical
Manufacturer	Circa Scientific, Inc.	Circa Scientific, Inc.	Identical
Product Code / Regulation	DXF / 21CFR 870.5175	DXF / 21CFR 870.5175	Identical
Indications for Use	The CrossWise RF Transseptal Cannula and Accessories are used to create an atrial septal defect in the heart. Secondary indications include infusing solutions including heparinized saline and mixtures of 50% contrast media and 50% saline.	The CrossWise RF Transseptal Cannula and Accessories are used to create an atrial septal defect in the heart. Secondary indications include infusing solutions including heparinized saline and mixtures of 50% contrast media and 50% saline.	Identical
Energy Delivery	RF (monopolar mode)	RF (monopolar mode)	Identical
Key Device Components	Cannula Handle with electrical connector and luer connector	Cannula Handle with electrical connector and luer connector	Identical
	Inner and outer polymer coated tubular stainless steel shaft	Inner and outer polymer coated tubular stainless steel shaft	Identical
	Radiopaque Shaft	Radiopaque Shaft	Identical
	RF Adapter Cable	RF Adapter Cable	Identical
	Dilator	Dilator	Identical
	Guidewire	Guidewire	Identical
Sizes / Dimensions	8.5F, 97cm, C1 Curve 13F, 97cm, C1 Curve	8.5F, 71cm, C1 Curve 8.5F, 97cm, C1 Curve 12F, 88cm, C1 Curve	Similar to PD; Subject Device adds 13F compatibility (for Faradrive sheath) with identical 12F extruded dilator. This does not raise new questions of safety or effectiveness

Feature	Subject Device	Predicate Device 1 (K241414)	Analysis of Differences
Guidewire Compatibility	0.032”	0.032”	Identical
Introducer Compatibility	CardioCurve Vizigo Faradrive	Agilis, Swartz Watchman FlexCath	Similar; Subject Device dilator extrusions are identical with minor proximal hub modifications for compatibility with new sheaths. This does not raise new questions of safety or effectiveness
Device Materials (Patient Contacting)	Handle: Polypropylene, White colorant Shaft: Stainless Steel, Adcoat 41-3500, White colorant Distal Tip: Stainless Steel Guidewire: Stainless Steel, PTFE Dilator Shaft: High Density Polyethylene, Barium Sulfate, Blue Colorant	Handle: Polypropylene, White colorant Shaft: Stainless Steel, Adcoat 41-3500, White colorant Distal Tip: Stainless Steel Guidewire: Stainless Steel, PTFE Dilator Shaft: High Density Polyethylene, Barium Sulfate, Blue Colorant	Identical
Packaging	Sterile Pouch with IFU in Shelf Carton	Sterile Pouch with IFU in Shelf Carton	Identical
Sterilization Method / SAL	EO / 10^{-6}	EO / 10^{-6}	Identical
Single-Use Devices?	Yes	Yes	Identical
Inserted Over a Guidewire?	Yes	Yes	Identical
Shelf-Life	2 Years	2 Years	Identical
Non-pyrogenic?	Yes	Yes	Identical
Connection Cable?	Yes	Yes	Identical
Single Use or Multi-Use Connection Cable?	Multi-Use (K243193)	Multi-Use (K243193)	Identical
Compatible RF Generator	ValleyLabs Force 2 Electrosurgical Generator	ValleyLabs Force 2 Electrosurgical Generator	Identical

Performance Standards

The CrossWise RF Transseptal Access System line extension models have been developed in conformance with the following standards:

- ISO 10993-1:2018, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- FDA Guidance: Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process", September 2023
- ISO 15223-1:2021, Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied
- ISO 20417:2021, Medical devices – Information to be supplied by the manufacturer
- ISO 11070-1:2014, Sterile single-use intravascular introducers, dilators and guidewires
- ISO 80369-7:2021, Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications

Nonclinical Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Bench Testing

The minor modifications for the CrossWise RF Transseptal Access System line extension models leveraged most of the performance data of the Predicate Device with the following exceptions:

- Dilator Hub Snap Compatibility
- Sheath Compatibility
- Dilator Leak Test
- Dilator Tensile
- ISO 80369-7 Luer Testing

As there was no change in material, design or processing that could lead to age related failure, no further stability/shelf-life testing was required. As there are no changes to the packaging system of the device, no further transportation or packaging stability testing was conducted beyond what has been reviewed under the Predicate Device K241414.

Conclusions

The CrossWise Transseptal Access System line extensions are identical to the Predicate Device cleared via K241414 with minor luer hub differences in the dilator component that enable compatibility with other commercial introducer sheaths. The non-clinical bench data supports the

safety of the device and demonstrates that the CrossWise Transseptal Access System line extensions perform as intended in the specified use conditions.

The CrossWise RF Transseptal Access System line extensions (**Table 4**) are substantially equivalent to the Predicate Device (**Table 3**).