November 26, 2024
Circa Scientific, Inc.
% Jennifer Willner
President
JW Regulatory Consulting LLC
406 Wacouta St, Suite 417
Saint Paul, Minnesota 55101

Re: K243193
Trade/Device Name: Cross Wise™ Multi-Use RF Adapter Cable
Regulation Number: 21 CFR 870.5175
Regulation Name: Septostomy catheter
Regulatory Class: Class II
Product Code: DXF
Dated: September 30, 2024
Received: October 31, 2024

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,

Alexandra K. Manaras -S

For Kalkidan Molla
Acting 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)*
K243193

Device Name
CrossWise RF Transseptal Access System (Models: CW-1085S, CW-1085A, CW-1012W, CW-1012C);
CrossWise RF Adapter Cable (Model CW-1002)

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.

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

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510(K) SUMMARY

510(k) Number: K243193

Date Prepared: October 31, 2024

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 with CrossWise™ Multi-Use RF Adapter Cable
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 with CrossWise Multi-Use RF Adapter Cable is substantially equivalent to the previously cleared predicate CrossWise RF Transseptal Access System with CrossWise RF Adapter Cable Predicate Device (**Table 3**).

Table 3: Predicate Devices

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

Device Description

The CrossWise Multi-Use RF Adapter Cable (Model CW-1001) is used in Transseptal Puncture Procedures (TSP) to connect the CrossWise™ RF Transseptal Cannula (K241414) to a 3/32" electrosurgical (ES) pencil. The cable delivers radiofrequency (RF) energy to the CrossWise™ RF Transseptal Cannula to facilitate septal puncture.

The CrossWise RF Transseptal Cannula is connected to a ValleyLabs Force2 ES Generator (K051644) via the CrossWise Multi-Use RF Adapter Cable (Model CW-1001) or CrossWise RF Adapter Cable (Model CW-1002 / K241414) and a commercially available 3/32" ES pencil. The CrossWise Multi-Use RF Adapter Cable has unique connectors on each end which cannot be connected to an improper device and/or accessory.

The CrossWise Multi-Use RF Adapter Cable (Model CW-1001) and CrossWise RF Adapter Cable (Model CW-1002) are both compatible with all CrossWise RF Transseptal Access System models. The dimensions for the CrossWise Multi-Use RF Adapter Cable can be found on the package labels.

Circa Scientific sterilized the CrossWise Multi-Use RF Adapter Cable via ethylene oxide (EO) for initial use and is intended for multiple patients use, following prescribed reprocessing instructions. The prescribed reprocessing includes cleaning and steam/autoclave sterilization procedures that have been validated for up to10 uses when users follow the cleaning and sterilization methods described in the Cleaning and Sterilization Instructions sections of the CrossWise Multi-Use RF Adapter Cable IFU.

The CrossWise Multi-Use RF Adapter Cable does not come into direct or indirect contact with the patient according to the definitions in Section 3.0 of ISO 10993-1, and Attachment G of the September 2023 FDA Guidance document.

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 Device

The Subject and Predicate Devices have identical technological elements and are used with the identical models of CrossWise RF Transseptal Access System. The CrossWise Multi-Use RF Adapter Cable and CrossWise RF Adapter Cable are both designed to deliver radiofrequency (RF) energy to the CrossWise RF Transseptal Cannula to facilitate septal puncture and have the same overall design, function, packaging and materials of construction.

The following technological differences exist between the Subject and Predicate Device:

- Ability to reprocess (clean and re-sterilize) the Subject Device up to 10 times for use on multiple patients
- Addition of a UDI heat shrink label on the Subject Device to enable identification throughout its lifetime as a reusable device
- Minor material modification to the connector shroud material (Santoprene 8281-65MED, Black (TPE)) to withstand autoclave temperatures
- Updated labeling:
    - New Pouch label and shelf carton label which do not have single use and do not reuse symbols
    - New IFU which provides validated reprocessing (cleaning and sterilization) instructions

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

Table 4: Substantial Equivalence Comparison Table

Feature	Subject Device	Predicate Device (K241414)	Analysis of Differences
Product Name	CrossWise RF Transseptal Access System with CrossWise Multi-Use RF Adapter Cable	CrossWise RF Transseptal Access System with CrossWise RF Adapter Cable	
Manufacturer	Circa Scientific, Inc.	Circa Scientific, Inc.	
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
Device Components / Sizes / Dimensions	Overall length: 3 meters	Overall length: 3 meters	Identical
	ES Pencil Adapter Pin OD: 0.093” Pin	ES Pencil Adapter Pin OD: 0.093” Pin	Identical
	Needle Connector: Staubli 2mm Plug	Needle Connector: Staubli 2mm Plug	Identical
	Number of conductors: 1	Number of conductors: 1	Identical
	Heat Shrink UDI Label	No label on device	Reusable devices are required to have permanent labeling on device; difference does not raise new questions of safety or effectiveness
Device Compatibility	• CrossWise 8.5Fr, 71cm C1 Swartz, Model CW-1085S • CrossWise 8.5Fr, 97cm C1 Agilis, Model CW-1085A • CrossWise 12Fr, 88cm C1 Watchman, Model CW-1012W	• CrossWise 8.5Fr, 71cm C1 Swartz, Model CW-1085S • CrossWise 8.5Fr, 97cm C1 Agilis, Model CW-1085A • CrossWise 12Fr, 88cm C1 Watchman, Model CW-1012W	Identical

Feature	Subject Device	Predicate Device (K241414)	Analysis of Differences
	• CrossWise 12Fr, 88cm C1 FlexCath, Model CW-1012C • ValleyLabs Force 2 Electrosurgical Generator	• CrossWise 12Fr, 88cm C1 FlexCath, Model CW-1012C • ValleyLabs Force 2 Electrosurgical Generator	
Device Materials	ES Pencil Adapter Overmold: Santoprene 8281-65MED, Black (TPE) Cable Jacket Material: TPE Bovie Pin: 316 Stainless Steel Needle Connector: TPE	ES Pencil Adapter Overmold: 45D Pebax Cable Jacket Material: TPE Bovie Pin: 316 Stainless Steel Needle Connector: TPE	Substantially similar; minor material difference does not raise new questions of safety or effectiveness as the device is non-patient contacting
Packaging	Sterile Pouch with IFU in Shelf Carton	Sterile Pouch with IFU in Shelf Carton	Identical
Sterilization Method / SAL	As distributed: EO / 10^{-6} By User: Steam (Autoclave) / 10^{-6}	As distributed: EO / 10^{-6}	Identical method and cycle as initially distributed; PD is a single-use device and not sterilized by the User
Single-Use Devices?	No	Yes	This is the main reason for this Special 510(k) submission
Shelf-Life	6M, however intend to extend up to 2 years upon successful completion of testing to identical protocol	6M, however intend to extend up to 2 years upon successful completion of testing to identical protocol	Identical

Performance Standards

The CrossWise RF Transseptal Access System with Multi-Use RF Adapter Cable has been developed in conformance with the following standards:

- ISO 11135:2014, Sterilization of health-care products - Ethylene oxide - Requirements for the development validation and routine control of a sterilization process for medical devices
- ISO 10993-7:2008, Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals
- 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

- AAMI TIR28:2016, Product adoption and process equivalence for ethylene oxide sterilization
- ISO 17665:2024, Sterilization of health care products - Moist heat - Requirements for the development validation and routine control of a sterilization process for medical devices
- AAMI TIR12:2020, Designing testing and labeling medical devices intended for processing by health care facilities: A guide for device manufacturers
- ANSI/AAMI ST79:2017, Comprehensive guide to steam sterilization and sterility assurance in health care facilities
- ANSI/AAMI ST98:2022, Cleaning validation of health care products - Requirements for development and validation of a cleaning process for medical devices
- IEC 60601-2-2:2023, 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

Nonclinical Performance Data

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

Sterilization

The CrossWise Multi-Use RF Adapter Cable is provided to the user in sterile condition using ethylene oxide (EO) sterilization. The Subject Device has been adopted into the identical EO sterilization cycle as the Predicate Device in accordance with ISO 11135:2014 *Sterilization of health-care products- Ethylene Oxide- Requirements for development, validation and routine control of a sterilization process for medical devices*. The sterile packaged CrossWise Multi-Use RF Adapter Cable is validated to meet a sterility assurance level (SAL) of 10^{-6}.

The modification subject to this Special 510(k) submission involves providing a multi-use device that can be reprocessed by the end user following the cleaning and sterilization instructions provided in the CrossWise Multi-Use RF Adapter IFU. As such, the CrossWise Multi-Use RF Adapter Cable has been validated to undergo up to 10 additional sterilization cycles using steam heat/autoclave sterilization methodology. This validation was conducted in accordance with ISO 17665:2024, *Sterilization of health care products - Moist heat - Requirements for the development validation and routine control of a sterilization process for medical devices*. The following standards were also considered during the reprocessing validation activities: AAMI TIR12:2020, *Designing testing and labeling medical devices intended for processing by health care facilities: A guide for device manufacturers*, ANSI/AAMI ST79:2017, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*, and ANSI/AAMI ST98:2022, *Cleaning validation of health care products - Requirements for development and validation of a cleaning process for medical devices*.

Bench Testing

Design verification testing was conducted to support the noted changes in the CrossWise Multi-Use RF Adapter Cable. Testing was conducted on devices at 2 aging points: after manufacturing (T=0) and after 6 months of accelerated aging (T=6M AA).

Devices were subsequently conditioned to reflect the intended reusability of the devices after reprocessing and passed the following testing:

- Label visual inspection
- Device visual inspection
- Dimensional verification
- Functional:
    - Impedance
    - Bend radius
    - Resistance
    - RF energy delivery
    - Continuity
    - Tensile
- Durability

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 RF Transseptal Access System with CrossWise Multi-Use RF Adapter Cable is identical to the CrossWise RF Transseptal Access System with CrossWise RF Adapter Cable cleared via K241414 with minor design differences of the cable (labeling and connector resin) that enable it to be reprocessed by the end user for multiple patient use. The non-clinical bench data supports the safety of the device and demonstrates that the CrossWise RF Transseptal Access System with CrossWise Multi-Use Adapter Cable performs as intended in the specified use conditions.

The CrossWise RF Transseptal Access System with CrossWise Multi-Use RF Adapter Cable is substantially equivalent to the Predicate Device (**Table 3**).