September 26, 2024

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

Re: K241414
Trade/Device Name: CrossWise RF Transseptal Access System (Models: CW-1085S, CW-1085A, CW-1012W, CW-1012C); CrossWise RF Adapter Cable (Model CW-1002)
Regulation Number: 21 CFR 870.5175
Regulation Name: Septostomy Catheter
Regulatory Class: Class II
Product Code: DXF
Dated: May 17, 2024
Received: May 17, 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)*
K241414

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.

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510(K) SUMMARY

510(k) Number: K241414

Date Prepared: September 26, 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 CrossWise™ 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 RF Adapter Cable is substantially equivalent to the previously cleared predicate Cross Vascular RF Transseptal Needle with Connection Cable Predicate Device (**Table 3**) and has aspects similar to those in the AcQCross Qx Integrated Transseptal Dilator/Needle Reference Device (**Table 4**).

Table 3: Predicate Devices

Predicate Device	Manufacturer	FDA 510(k)
Cross Vascular RF Transseptal Needle	Cross Vascular, Inc.	K232852

Table 4: Reference Device

Reference Device	Manufacturer	FDA 510(k)
AcQCross Qx Transseptal Dilator/Needle	Acutus Medical	K220047

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 RF Adapter Cable (packaged separately – Model CW-1002) 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 four configurations compatible with various commercially available guide sheaths (**Table 5**). All four configurations require use of a single model (CW-1002) CrossWise RF Adapter Cable Model which is packaged separately.

Table 5: Compatible Introducer Sets

CrossWise 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
CrossWise 8.5Fr, 97cm C1 Agilis	CW-1085A	Agilis NxT Steerable Introducer 8.5Fr, 71cm, Small, Medium, Large Curl [St Jude Medical / Abbott]	408309 408310 G408324
CrossWise 12Fr, 88cm C1 Watchman	CW-1012W	Watchman [Boston Scientific]	M635TU70010
CrossWise 12Fr, 88cm C1 FlexCath	CW-1012C	FlexCath Advance Steerable Sheath 12F [Medtronic]	4FC12

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 Subject and Predicate (PD) and Reference (RD) Devices are based on the same technological elements of delivering RF power in a monopolar mode between their distal tip electrode and commercially available Patient Return Electrode. Both devices are also loaded through commercially available transseptal introducer sets and have connections at their proximal end to a RF generator. The Subject and PD/RD devices both contain holes at the distal end to facilitate injection of contrast solution.

The following technological differences exist between the Subject and PD/RD device(s):

- Materials of construction
- Inner lumen dielectric coating
- Tip electrode geometry
- Tip protrusion indicator sleeve

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

Table 6: Substantial Equivalence Comparison Table

Feature	Subject Device	Predicate Device 1 (K232852)	Reference Device 2 (K220047)	Analysis of Differences
Product Name	CrossWise RF Transseptal Access System	Cross Vascular RF Transseptal Needle	AcQCross Qx Integrated Transseptal Dilator/Needle	
Manufacturer	Circa Scientific, Inc.	Cross Vascular, Inc.	Acutus Medical, Inc.	
Product Code / Regulation	DXF / 21CFR 870.5175	DXF / 21CFR 870.5175	DYB, DRE / 21CFR 870.1340	Identical to PD
Indications for Use	The CrossWise RF Transseptal System is 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 Cross Vascular RF Transseptal Needle is 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 AcQCross™ Qx Integrated Transseptal Dilator/Needle is indicated to puncture the interatrial septum to gain access to the left side of the heart whereby various cardiovascular catheters are introduced.	Identical to PD; Same as RD with addition of infusing solutions
Energy Delivery	RF (monopolar mode)	RF (monopolar mode)	RF (monopolar mode)	Identical to PD & RD
Key Device Components	Cannula Handle with electrical connector and luer connector	Needle Handle with electrical connector and luer connector	Integrated Dilator/Needle Handle with electrical connector and luer connector	Equivalent to PD & RD
	Inner and outer polymer coated tubular stainless steel shaft	Outer polymer coated SST Shaft	Elongated shaft with tapered tip and central lumen to track over guidewire. Hollow stainless steel transseptal needle. Shaft and needle connected to proximal handle.	Similar to PD & RD; minor design differences do not raise new questions of safety or effectiveness
	Radiopaque Shaft	Radiopaque Shaft/Tip	Radiopaque Shaft/Tip	Identical to PD & RD
	RF Adapter Cable	Connection Cable	Adapter Cables – EGM & ES	Identical to PD & RD
	Dilator		Integrated dilator/needle	Similar – PD relies on dilator from Introducer Set while RD has

Feature	Subject Device	Predicate Device 1 (K232852)	Reference Device 2 (K220047)	Analysis of Differences
				integrated dilator/needle; Minor design differences do not raise new questions of safety or effectiveness
	Guidewire		Guidewire	Identical to RD
Sizes / Dimensions	8.5F, 71cm, C1 Curve 8.5F, 97cm, C1 Curve 12F, 88cm, C1 Curve	8.5F, 71cm, C0 Curve 8.5F, 71cm, C1 Curve 8.5F, 98cm, C0 Curve 8.5F, 98cm, C1 Curve	8.5F, 61cm 8.5F, 71cm 8.5F, 63cm 12F, 65cm 12F, 70cm	Similar to PD & RD; Subject Device not available in 61-65cm lengths but does not raise new questions of safety or effectiveness
Guidewire Compatibility	0.032”	0.032”	0.032”	Identical to PD & RD
Introducer Compatibility	Agilis, Swartz Watchman FlexCath	Agilis, Swartz	Heartspan Watchman FlexCath Agilis, Swartz Vizigo	Similar; Subject Device not compatible with all of RD compatible devices but 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, blue colorant Shaft: 304 Stainless Steel, Adcoat 41-3500, blue colorant Distal Tip: Gold	Shaft: Polyethylene Hexene Copolymer; ethylene homopolymer; barium sulfate with blue colorant Needle: 304 Stainless steel Hypotube: 304 stainless steel Luer fitting: polycarbonate	Similar; minor design differences do not raise new questions of safety or effectiveness
Packaging	Sterile Pouch with IFU in Shelf Carton	Sterile Pouch with IFU in Shelf Carton	Sterile Pouch with IFU in Shelf Carton	Identical to PD & RD

Feature	Subject Device	Predicate Device 1 (K232852)	Reference Device 2 (K220047)	Analysis of Differences
Sterilization Method / SAL	EO / 10^{-6}	EO / 10^{-6}	EO / 10^{-6}	Identical to PD & RD
Single-Use Devices?	Yes	Yes	Yes	Identical to PD & RD
Inserted Over a Guidewire?	Yes	No	Yes	Identical to RD
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	12 Months	Identical to PD
Non-pyrogenic?	Yes	Yes	Yes	Identical to PD & RD
Connection Cable?	Yes	Yes	Yes	Identical to PD & RD
Single Use or Multi-Use Connection Cable?	Single Use	Single Use	Single Use	Identical to PD & RD
Compatible RF Generator	ValleyLabs Force 2 Electrosurgical Generator	Cross Vascular RF Generator RFG-01-00	Valleylabs Force 2 Electrosurgical Generator	Identical to RD

Performance Standards

The CrossWise RF Transseptal Access System has 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
- IEC 60601-1:2020, Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance
- IEC 60601-1-2:2014+A1:2020, Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements And Tests
- 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
- 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
- AAMI TIR42:2021 Evaluation of Particulate Associated with Vascular Medical Devices
- ISO 11607-1:2019, Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems
- ASTM D4169:2022, Standard Practice for Performance Testing of Shipping Containers and Systems
- 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.

Biocompatibility

Biocompatibility testing was performed on the CrossWise RF Transseptal Access System in accordance with ISO 10993-1, *Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process*. The panel of biocompatibility testing included the following recommended tests:

- Cytotoxicity
- Irritation/Intracutaneous Reactivity
- Acute Systemic Toxicity
- Sensitization
- Hemocompatibility:
  - Hemolysis, Direct and Indirect Methods
  - Complement Activation
  - Partial Thromboplastin Time (PTT)
  - Heparinized Platelet and Leukocyte (PL&L) Count Assay with Comparison Article
  - In Vivo Thrombogenicity in Canine
- Material Mediated Pyrogenicity

The results demonstrate that the CrossWise RF Transseptal Access System meets the requirements of ISO 10993-1 and is biocompatible for its intended use.

Sterilization

Sterilization validation adoption was performed on the CrossWise RF Transseptal Access System with CrossWise RF Adapter Cable 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 CrossWise RF Transseptal Access System with CrossWise RF Adapter Cable is subjected to a similar ethylene oxide (EO) sterilization process as the Predicate Devices to meet a sterility assurance level (SAL) of 10^{-6}.

Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety and EMC testing were conducted on the CrossWise RF Transseptal Access System with CrossWise RF Adapter Cable. The testing complies with the applicable sections of IEC 60601-1:2020, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance,* IEC 60601-1-2: 2014 +A1: 2020, *Medical electrical equipment – Part 1-2: General requirements for the basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests, and* 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.

This testing is consistent with that conducted by the Predicate Devices.

Bench Testing

Design verification testing was performed on the CrossWise RF Transseptal Access System with CrossWise RF Adapter Cable at two time points: immediately after manufacturing (T=0) and after six months of accelerated aging (T=6M AA). Devices were subjected to 2X sterilization and distribution simulation before the following types of testing was conducted:

CrossWise RF Transseptal Access System:

- Packaging Integrity
- Label Integrity
- Visual & Dimensional
- Introducer Set Compatibility
- Electrical Functionality/Compatibility
- Electrical Safety
- Mechanical Functionality
- Mechanical Durability
- Puncture Performance
- Particulate Generation
- Radiopacity
- Corrosion Resistance

CrossWise RF Adapter Cable:

- Packaging Integrity
- Label Integrity
- Visual & Dimensional
- Electrical Functionality and Compatibility
- Electrical Safety
- Mechanical Functionality
- Mechanical Durability

Conclusions

The CrossWise RF Transseptal Access System with CrossWise RF Adapter Cable is of similar materials and design of the PD/RD devices and has similar technical requirements. The non-clinical bench data support the safety of the device and demonstrate that the CrossWise RF Transseptal System performs as intended in the specified use conditions.

The CrossWise RF Transseptal Access System with CrossWise RF Adapter Cable is substantially equivalent to the Predicate (**Table 3**) and Reference (**Table 4**) Devices.