October 12, 2023

Cross Vascular Inc.
℅ Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K232852
Trade/Device Name: Cross Vascular RF Transseptal Needle, Cross Vascular Connection Cable
Regulation Number: 21 CFR 870.5175
Regulation Name: Septostomy catheter
Regulatory Class: Class II
Product Code: DXF
Dated: September 14, 2023
Received: September 14, 2023

Dear Prithul Bom:

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,

Rachel E. Neubrander -S

Rachel Neubrander
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)*
TBD

Device Name
Cross Vascular RF Transseptal Needle
Cross Vascular Connection Cable

Indications for Use *(Describe)*
The Cross Vascular RF Transseptal Needle and Connection Cable 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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5.0 510(K) SUMMARY

510(k) Number: K232852

Date Prepared: July 14, 2023

Table 1: Submitter Information

Manufacturer: Cross Vascular Inc. 535 Stevens Ave West Solana Beach, CA 92075 US FDA ERN: Pending	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	Cross Vascular RF Transseptal Needle Cross Vascular Connection Cable
Common Name	RF Transseptal Needle Connection Cable
Classification Name	Catheter, Septostomy
Regulation	21CFR 870.5175
Product Code	DXF
Regulatory Classification:	Class II
Device Panel:	Cardiovascular

The Cross Vascular Transseptal Needle device is substantially equivalent to the previously cleared predicate NRG Transseptal Needle (**Table 3**) which has not been subject to a design-related recall.

Table 3: Predicate Devices

Predicate Device	Manufacturer	FDA 510(k)
NRG Transseptal Needle	Boston Scientific (formerly Baylis Medical)	K073326

5.1 Device Description

The Cross Vascular RF Transseptal Needle is used in transseptal surgical procedures to puncture the fossa ovalis and gain access from the right side of the heart to the left atrium. The RF Transseptal Needle within a compatible transseptal introducer set (**Table 4**) along with radiofrequency (RF) energy from the RF Generator is used to facilitate the septal puncture.

The RF Transseptal Needle delivers RF power in a monopolar mode between the device's distal electrode and a commercially available external Patient Return Electrode (PRE) which is in compliance with IEC 60601-2-2. The RF Transseptal Needle is loaded through a compatible transseptal sheath and dilator (**Table 4**) and is connected at its proximal end to the Cross Vascular RF Generator via the Cross Vascular Connection Cable.

The RF Transseptal needle and Connection Cable are packaged individually in a single use, sterile package. All other components required for the transseptal procedure are NOT included in the package with the RF Transseptal Needle or in the package with the Connection Cable.

The distal end of the needle contains a small through hole to facilitate injection of contrast solution. The active tip is specially shaped to be atraumatic to the cardiac tissue until RF energy is applied.

Table 4 provides a list of introducer sets that have been determined to be compatible with the Cross Vascular RF Transseptal Needles. These introducer sets include an 8.5 Fr dilator whose ID is compatible with an 0.032" guidewire. Therefore, the RF Transseptal Needle has an OD compatible to meet this 0.032" dilator ID requirement.

Table 4: Compatible Introducer Sets

Cross Vascular RF Transseptal Needle		Compatible Commercial Introducer Set	
Description	**REF**	**Description**	**REF**
Sterile, RF needle, 71cm, C0, Standard Curve	RFN-71-CO	Swartz Braided Transseptal Guiding Introducer, 8.5Fr x 63, SL0 and SL1	407451 407453
Sterile, RF needle, 71cm, C1, Large Curve	RFN-71-C1		
Sterile, RF needle, 98cm, C0, Standard Curve	RFN-98-CO	Agilis NxT Steerable Introducer, 8.5Fr x 71cm	G408320 G408321 G408324
Sterile, RF needle, 98cm, C1, Large Curve	RFN-98-C1		

5.2 Indications for Use

The Cross Vascular RF Transseptal Needle with Connection Cable 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.

5.3 Comparison of Technological Characteristics with the Predicate Device

The Subject and Predicate 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. The Subject Device has been validated with Covidien's Valleylab Model E7507 Patient Return Electrode. Both devices are also loaded through commercially available transseptal introducer sets and attach a Connection Cable to their proximal end which is connected to an RF generator. The Subject and Predicate Devices both contain holes at the distal end to facilitate injection of contrast solution.

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

- Materials of construction

- Predicate Device can optionally be connected to an external pressure monitoring system to monitor cardiac pressures
- Predicate Device provides a reusable connector cable

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

Table 5: Substantial Equivalence Comparison Table

Feature	Subject Device	Predicate Device (K073326)	Conclusion
Product Name	Cross Vascular RF Transseptal Needle	NRG Transseptal Needle	
Manufacturer	Cross Vascular, Inc.	Boston Scientific (formerly Baylis Medical)	
Product Code / Regulation	DXF / 21CFR 870.5175	DXF / 21CFR 870.5175	Identical
Indications for Use	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.	Creation of an atrial septal defect in the heart. Secondary applications include transseptal heart access, monitoring intracardiac pressures, sampling blood, and infusing solutions	Similar; Subject Device is not designed to monitor intracardiac pressures or sampling of blood but does not raise new questions of safety or effectiveness
Energy Delivery	RF (monopolar mode)	RF (monopolar mode)	Identical
Key Device Components	Handle with Connector	Handle with Connector	Identical
	Polymer Coated SST Shaft	Polymer Coated SST Shaft	Identical
	Radiopaque Distal Tip	Radiopaque Distal Tip	Identical
	Connection Cable	Connection Cable	Identical
Length & Curve	71cm, Standard Curve (C0) 71cm, Large Curve (C1) 98cm, Standard Curve (C0) 98cm, Large Curve (C1)	56cm, Curve C0 71cm, Curve C0 71cm, Curve C1 89cm, Curve C0 89cm, Curve C1 98cm, Curve C0 98cm, Curve C1	Similar; Subject Device not available in 56cm and 89cm lengths but does not raise new questions of safety or effectiveness
OD	Proximal: 0.047” (1.2 mm) Distal: 0.032” (0.8 mm)	Proximal: 1.2 mm Distal: 0.74mm	Nearly Identical

Feature	Subject Device	Predicate Device (K073326)	Conclusion
Dilator ID Compatibility	0.032”	0.032”	Identical
Device Materials (Patient Contacting)	Handle: Polypropylene Shaft: 304 Stainless Steel, Adcoat 41-3500 Distal Tip: Gold	Handle: Unknown polymer (ABS suspected) Shaft: 304 Stainless Steel; unknown polymer jacket (Pebax suspected) Distal Tip: Platinum/Iridium	Similar; minor design differences do not raise new questions of safety or effectiveness
Packaging	Sterile Pouch with IFU in Shelf Carton	Rigid Tray in Sterile Pouch with IFU in Shelf Carton	Similar; minor design differences do not raise new questions of safety or effectiveness
Sterilization Method / SAL	EO / 10^{-6}	EO / Not disclosed	Identical
Single-Use Devices?	Yes	Yes	Identical
Radiopaque?	Yes	Yes	Identical
Inserted Over a Guidewire?	No	No	Identical
Shelf-Life	6M, however intend to extend up to 2 years upon successful completion of testing to identical protocol	Unknown, suspect 3 years	Similar; minor difference in shelf-life does not raise new questions of safety or effectiveness
Non-pyrogenic?	Yes	Yes	Identical
Connection Cable?	Yes	Yes	Identical
Single Use or Multi-Use Connection Cable?	Single Use	Multi-Use	Similar; minor design difference does not raise new questions of safety or effectiveness

Feature	Subject Device	Predicate Device (K073326)	Conclusion
Compatible RF Generator	Cross Vascular RF Generator RFG-01-00	BMC RF Puncture Generator RFP-100A and RFP-100	Similar; design difference does not raise new questions of safety or effectiveness

5.4 Performance Standards

The Cross Vascular RF Transseptal Needle has been developed in conformance with the following standards and FDA guidance, as applicable:

- 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 2020
- IEC 60601-1:2005+A1:2012, Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance
- IEC 60601-1-2:2014, Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements and Tests
- IEC 60601-2-2:2017, 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 11135-1:2014, 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 10555-1:2013, Intravascular catheters — Sterile and single-use catheters — Part 1: General requirements
- ISO 80369-7:2021, Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications

5.5 Nonclinical Performance Data

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

5.5.1 Biocompatibility

Biocompatibility testing was performed on the Cross Vascular RF Transseptal Needle in accordance with ISO 10993-1:2018, 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
  - 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 Cross Vascular RF Transseptal Needle meets the requirements of ISO 10993-1 and is biocompatible for its intended use.

5.5.2 Sterilization

Sterilization validation was performed on the Cross Vascular RF Transseptal Needle 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 Cross Vascular RF Transseptal Needle is subjected to a similar ethylene oxide (EO) sterilization process as the Predicate Device to meet a sterility assurance level (SAL) of 10^{-6}.

5.5.3 Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety and EMC testing were conducted on the Cross Vascular RF Transseptal Needle. The testing complies with the applicable sections of IEC 60601-1:2005+A1:2012, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance,* IEC 60601-1-2:2014, *Medical electrical equipment – Part 1-2: General requirements for the basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests,* and IEC 60601-2-2:2017, *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 Device, NRG Transseptal Needle (K073326).

5.5.4 Bench Testing

Design verification testing was performed on the Cross Vascular RF Transseptal Needle and Connection 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:

- Visual & Dimensional
- Introducer Set Compatibility
- Electrical Functionality
- Mechanical Functionality
- Mechanical Durability
- Particulate
- Radiopacity
- Corrosion Resistance
- Packaging Integrity
- Label Integrity

5.6 Conclusions

The Cross Vascular RF Transseptal Needle is of similar materials and design of the Predicate Devices and has similar technical requirements. The devices perform as intended and present no unacceptable risks to the intended patient population or end user. The non-clinical bench data support the safety of the device and demonstrate that the Cross Vascular RF Transseptal Needle performs as intended in the specified use conditions.

The Cross Vascular RF Transseptal Needle with Connection Cable is substantially equivalent to the Predicate Device, NRG Transseptal Needle (K073326).