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: K232809
Trade/Device Name: Cross Vascular RF Generator and Footswitch (optional accessory)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: September 12, 2023
Received: September 12, 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,

Colin K. Chen -S

for

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control 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)*
K232809

Device Name
Cross Vascular RF Generator and Footswitch (optional accessory)

Indications for Use *(Describe)*

The Cross Vascular RF Generator and Footswitch (optional accessory) are to be used with separately cleared RF puncture devices in cardiovascular transseptal access procedures to create an atrial septal defect.

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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1.0 510(K) SUMMARY

510(k) Number: K232809

Date Prepared: September 12, 2023

Table 1: Submitter Information

Manufacturer: Cross Vascular Inc. 535 Stevens Ave West Solana Beach, CA 92705 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 Generator and Footswitch (optional accessory)
Common Name	Radiofrequency Generator
Classification Name	Electrosurgical, Cutting & Coagulating & Accessories
Regulation	21CFR 878.4400
Product Code	GEI
Regulatory Classification:	Class II
Device Panel:	General & Plastic Surgery

The Cross Vascular RF Generator device is substantially equivalent to the previously cleared predicate RF Puncture Generator (**Table 3**). Neither of these devices have been subject to a design-related recall.

Table 3: Predicate Device

Predicate Device	Manufacturer	FDA 510(k)
Baylis Medical Company Radiofrequency Perforation Generator, Model RFP-100A and optional footswitch (Model: RFA-FS)	Boston Scientific [formerly Baylis Medical]	K122278

5.1 Device Description

The Cross Vascular RF Generator (**Figure 1**) is a rechargeable battery-operated device used with compatible, separately cleared RF Transseptal Needles (i.e., Cross Vascular Models RFN-XX-CX) which are connected to the RF Generator through a Cross Vascular Connection Cable. The RF Generator delivers power in a monopolar mode between the distal tip electrode and a commercially available patient return electrode such as the Valleylabs Patient Return Electrode Model #E7507. An optional Cross Vascular Footswitch may be used with the RF Generator. Refer to **Table 4** for the Model Numbers of the Cross Vascular RF Generator and accessory devices covered by this application.

Table 4: Model Numbers for Subject Device and Accessories

Device Name/Description	Model Number
Cross Vascular RF Generator	RFG-01-00
Cross Vascular RF Generator Battery	RFG-01-BT
Cross Vascular RF Generator Replacement Charger	RFG-01-CG

Device Name/Description	Model Number
Cross Vascular RF Generator Footswitch	RFG-01-FS

The Cross Vascular RF Generator is used with Cross Vascular RF Transseptal Needles 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 Generator is used to provide RF energy through the Connection Cable and into the RF Transseptal Needle to facilitate the septal puncture.

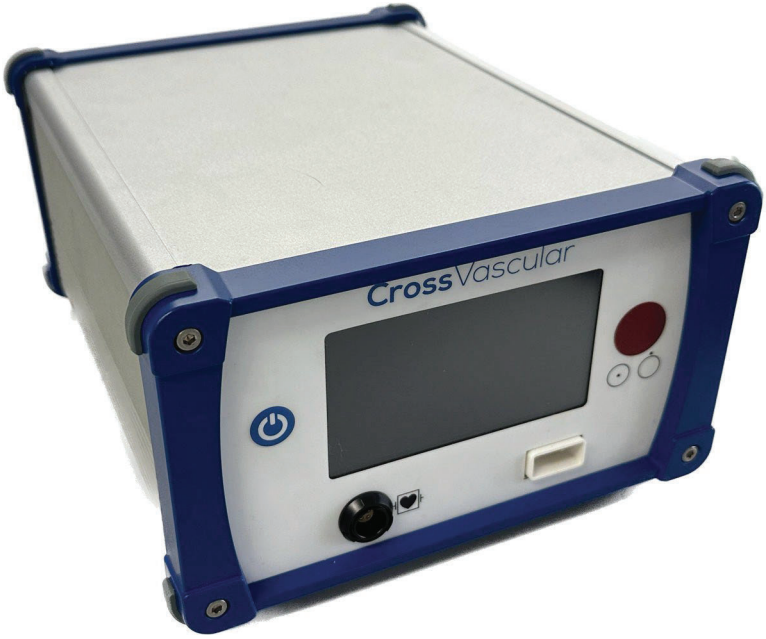

Figure 1: Cross Vascular RF Generator

5.2 Indications for Use

The Cross Vascular RF Generator and Footswitch (optional accessory) are to be used with a separately cleared RF puncture devices in cardiovascular transseptal access procedures to create an atrial septal defect.

5.3 Comparison of Technological Characteristics with the Predicate Device

The Subject and Predicate Devices are based on the same technological elements of generating, controlling and delivering RF power in a monopolar mode between the distal tip electrode of an RF device and commercially available Patient Return Electrode. The Subject and Predicate Devices both connect to RF devices through a connection cable, are electrically powered and have an optional, separately provided footswitch.

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

- The Subject Device is battery-powered while the Predicate Device requires plug into a properly grounded AC mains.
- The Subject Device has a lower maximum power output (25 Watts) than the Predicate Device maximum power output (50 Watts).

- The Subject Device only outputs power in a continuous monopolar mode while the Predicate Device allows for power output in a continuous monopolar mode and a pulse mode.

These differences provide convenience and efficiency over the Predicate Device and do not impact the intended use. No new questions regarding safety or effectiveness arise from this difference.

Table 5: Substantial Equivalence Comparison Table

Description	Subject Device	Predicate Device (K122278)	Conclusion
Product Name	Cross Vascular RF Generator	Radiofrequency Puncture Generator	
Manufacturer	Cross Vascular, Inc.	Boston Scientific [formerly Baylis Medical]	
Product Code / Regulation	GEI / 21CFR 878.4400	GEI / 21CFR 878.4400	Identical
Indications for Use	The Cross Vascular RF Generator and Footswitch (optional accessory) are to be used with separately cleared RF puncture devices in cardiovascular transseptal access procedures to create an atrial septal defect.	The Baylis Medical Company Radiofrequency Puncture Generator & Footswitch (optional accessory) is to be used with separately approved radiofrequency devices in general surgical procedures to cut soft tissues.	Similar. Subject and Predicate devices are used in the identical cardiovascular transseptal access procedures to create an atrial septal defect. Subject device is not intended to be used for general surgical procedures.
Device Components	RF Generator	RF Generator	Identical
	Battery	N/A – device is not battery operated	Similar; minor design differences do not raise new questions of safety or effectiveness. The use of a battery and charger also increases the device portability. The device can be brought in during the procedure and placed without the concern of being able to reach a wall outlet, having cords entangled or in the way of operations. When the procedure is completed, the device can easily be moved and plugged into the charger as needed. Battery-powered devices and their associated charging are commonly used, and charging is standard practice across all battery-powered devices.
	Charger		
	Footswitch (optional)	Footswitch (optional)	Identical
Energy Delivery Type	Radiofrequency 462 kHz, Sinusoidal	Radiofrequency 468 kHz, Sinusoidal	Near identical

CrossVascular

RF Generator 510(k) Summary

Description	Subject Device	Predicate Device (K122278)	Conclusion
Power Source	Lithium Ion Battery	AC Mains	Similar; minor design differences do not raise new questions of safety or effectiveness. Battery-powered devices reduce patient risks associated with AC mains connections as there is no risk of power surges through the device, accidental power loss via unplugging the device, etc. The effectiveness of the device is not affected by the use of a battery as the battery is capable of delivering the required power to complete the transseptal puncture (TSP) procedure. Further it is shown to be capable of maintaining RF power output within the specified accuracy range.
Output Power	Maximum 25 Watts	Maximum 50 Watts	Similar; minor design differences do not raise new questions of safety or effectiveness. The subject device has a lower maximum output power than the predicate, which does not add new risks of patient or user harms which stem from high RF power output. The listed maximum output power for the subject device is sufficient to effectively execute a TSP procedure.

Description	Subject Device	Predicate Device (K122278)	Conclusion
Output Current	Maximum 0.5 A	Maximum 1.27 A	Similar; minor design differences do not raise new questions of safety or effectiveness. The subject device has a lower maximum current output than the predicate device, which does not add any new risks of patient or user harm from high current complications.
Output Voltage	Maximum 246 V	Maximum 565.77 V	Similar; minor design differences do not raise new questions of safety or effectiveness. The subject device has a lower maximum voltage output than the predicate device, which does not add any new risks of patient or user harm from high voltage complications.
Measurement Accuracy: Power & Impedance	Impedance Range / Accuracy 200-800 ohm: ± 10% 800-3500 ohm: ± 20%	Impedance Range / Accuracy 100-1000 ohm: ± 10% 1000-3200 ohm: ± 15% 3200-6000 ohm: ± 20%	Similar; minor design differences do not raise new questions of safety or effectiveness. The subject device operates over a narrower range of impedance since the subject device is only intended for use in TSP procedures. This narrower impedance range does not impede the subject device's ability to deliver the appropriate power for TSP. User and patient safety are not adversely affected because the maximum voltage output of the device is lower than the predicate device.

Description	Subject Device	Predicate Device (K122278)	Conclusion
Output Modes	Single Mode, 100% Duty Cycle	Mode 10, Constant, 100% Duty Cycle Mode 10, Pulse, 30% Duty Cycle Mode 12, Constant, 100% Duty Cycle Mode 12, Pulse, 30 % Duty Cycle Mode 14, STX Low, 1.5% Duty Cycle Mode 14, STX High, 1.5% Duty Cycle	The subject device only has one mode with 100% duty cycle as it is dedicated to TSP procedures. The various modes offered by the predicate allow for use in ablation procedures. By offering fewer modes, the subject device does not add any new risks of patient or user harm from incorrect setting choices.
Output Polarity	Monopolar	Monopolar	Identical
Neutral Electrode Type	Conductive	Conductive	Identical
Dimensions	Width: 7.8 inches (19.8cm) Length: 9.7 inches (24.6 cm) Height (legs closed): 4.9 inches (12.4 cm) Height (legs extended): 6.2 inches (12.7 cm)	Width: 11.25 inches (28.5 cm) Length: 15.6 inches (39.6 cm) Height: 7 inches (17.8 cm)	Similar; minor design differences do not raise new questions of safety or effectiveness. The subject device is smaller than the predicate device, making the subject device more conducive for use in a crowded operating room. There are no new risks to the user or patient introduced by the reduced size of the device.

Weight	5.5lb. (2.5 kg)	20 lb. (9.1 kg)	Similar; minor design differences do not raise new questions of safety or effectiveness. The subject device is lighter than the predicate device, making the subject device more conducive for use in a crowded operating room. There are no new risks to the user or patient introduced by the reduced weight of the device.

Description	Subject Device	Predicate Device (K122278)	Conclusion
Storage Environmental Requirements	Temp: -20°C to 50°C Humidity: □90%, non-condensing Pressure: 500 to 1060 millibar	Temp: -20°C to 50°C Humidity: □90%, non-condensing Pressure: 500 to 1060 millibar	Identical
Operating Environmental Requirements	Temp: 15°C to 40°C Humidity: 15% to 90%, non-condensing Pressure: 700 to 1060 millibar	Temp: 15°C to 40°C Humidity: 15% to 90%, non-condensing Pressure: 700 to 1060 millibar	Identical

5.4 Performance Standards

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

- 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
- IEC 62133-2:2017, Safety requirements for portable sealed secondary cells
- 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 60417:2002, Graphical symbols for use on equipment

5.5 Nonclinical Performance Data

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

Software and Bench Testing

The Cross Vascular RF Generator software (SW) is custom software responsible for controlling the user interface and all device settings and outputs. The Cross Vascular SW integrates user input to control the following 5 device states:

- Standby State
- Ready State

- RF On State
- Alert State
- Error State

The Cross Vascular SW is considered a Major Level of Concern whose risk has been appropriately assessed and mitigated and has undergone software validation testing. As the RF Generator is not Wi-Fi enabled or connected to hospital systems or programs, there is no cybersecurity concern.

Bench Testing

Design verification testing was conducted on the Cross Vascular RF Generator and accessories (Battery, Charger & Footswitch) after being subjected to simulated transit conditions. The following types of testing were conducted:

- Transit Testing
- Labeling Verification
- Visual Inspection
- Unit Verification
    - Weight
    - Operational States
    - Battery Discharge
    - Display
- Cleaning Verification
- Functionality
    - Electrical
    - Footswitch
    - Battery
    - Alerts
- Compatibility
    - Footswitch
    - Battery
    - Charger
- Durability

Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety and EMC testing were conducted on the Cross Vascular RF Generator. 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 Baylis Medical Company Radiofrequency Perforation Generator, Model RFP-100A and optional footswitch (Model: RFA-FS) (K122278).

5.6 Conclusions

The Cross Vascular RF Generator is of similar design to the Predicate Device and has similar technical requirements. The RF Generator performs as intended and presents no unacceptable risks to the intended patient population or end user. The software validation, electrical compatibility and safety testing, and non-clinical bench data support the safety of the device and demonstrate that the Cross Vascular RF Generator performs as intended in the specified use conditions.

The Cross Vascular RF Generator is substantially equivalent to the Predicate Device, Baylis Medical Company Radiofrequency Perforation Generator, Model RFP-100A and optional footswitch (Model: RFA-FS) (K122278).