



October 25, 2023

Starmed Co., Ltd.
% Minsu Kim
SR Consultant
Mdas
#302, 35, Dongtansancheok-ro 1-gil
Hwaseong-si, Gyeonggi-do 18488
Korea, South

Re: K222997

Trade/Device Name: VVR Generator system
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: September 22, 2023
Received: September 22, 2023

Dear Minsu Kim:

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,

Mark

Trumbore -S

Mark Trumbore, Ph.D.

Assistant Director

DHT4A: Division of General Surgery Devices

OHT4: Office of Surgical

and Infection Control Devices

Digitally signed by Mark
Trumbore -S

Date: 2023.10.25 08:58:21
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Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K222997

Device Name
VVR Generator System

Indications for Use (Describe)

VVR Generator system is intended for endovascular coagulation of Saphenous Veins in patients with superficial vein reflux.

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

K222997

1. SUBMITTER INFORMATION

- Manufacturer: STARMED CO., LTD.
B-Dong, 4F&12F, 158, Haneulmaeul-Ro. Ilsandong-Gu, Goyang-Si
Gyeonggi, Republic of Korea
- Contact Person: Honggeun Lee/Q&R senior manager
Tel) +82-31-816-3546(209)
Fax) +82-31-816-4546
Email) lhg1186@STARmed4u.com
- Date Prepared: September 26, 2022

2. DEVICE INFORMATION

- Trade Name: VVR Generator system
- Common Name: Electrosurgical System
- Regulation Number: 21 CFR 878.4400
- Regulation Name: Electrosurgical, Cutting & Coagulation & Accessories
- Regulation Class: Class II
- Product Code: GEI
- Review Panel: General & Plastic Surgery

3. PREDICATE DEVICE INFORMATION

- Predicate Device (A): K040638 (VNUS Radiofrequency Generator, Model RFG2)
- Predicate Device (B): K111887 (ClosureFAST Radiofrequency Catheter)

4. DESCRIPTION OF THE DEVICE

VVR Generator System consists of Generator (VVR Generator), Active electrode (VENISTAR) and accessory such as foot switch and cooling pump.

The generator generates, controls and monitors RF energy and delivers energy to the active electrode.

The active electrode has an active coil and a receiver coil that allow the RF energy to flow through the tissue. The RF energy raises the temperature in the tissue, causing coagulation and occlusion of blood vessels.

The single footswitch works as an on/off switch and the double footswitch works to increase or decrease the power output.

A cooling pump circulates water around the electrodes to reduce the temperature of the electrodes and prevent tissue sticking to the electrodes.

5. INDICATION FOR USE

VVR Generator system is intended for endovascular coagulation of Saphenous Veins in patients with superficial vein reflux.

6. TECHNICAL CHARACTERISTICS

Comparison Item		Subject Device	Predicate Device (A)	Predicate Device (B)
510(k) Number		K222997	K040638	K111887
Proprietary Name		VVR Generator, VIVA Pump, VENISTAR	VNUS Radiofrequency Generator	ClosureFAST Radiofrequency Catheter
Model Number		VVR10, VP01, VP01-1, 3-VENI0030N, 7-VENI0070N, 3-VENI003090N, 7-VENI007090N	Model RFG2	-
Manufacturer		STARMED CO., LTD.	VNUS Medical Technologies, Inc.	Covidien
Regulatory Class		Class II	Class II	Class II
Regulation Number		21 CFR 878.4400	21 CFR 878.4400	21 CFR 878.4400
Product Code		GEI	GEI	GEI
Indication for Use		VVR Generator system is intended for endovascular coagulation of Saphenous Veins in patients with superficial vein reflux.	The VNUS Radiofrequency Generator is intended for use with VNUS radiofrequency devices intended for vessel and tissue coagulation.	The VNUS ClosureFAST Catheter is intended for endovascular coagulation of blood vessels in patients with superficial vein reflux
Prescription or OTC		Prescription	Prescription	Prescription
Generator	Monopolar or Bipolar	Bipolar	Bipolar	
	Temperature sensors	N/A	10°C - 130°C	
	Impedance monitor	10-800 ohms	N/A	
	Continuity monitor	Impedance and Output	Temperature and Output	
	Output frequency	480 kHz±10%	460.8 kHz,	
	Power output	Max power output ≤40W@Venistar Mode	6 W/cm (40 W into catheter 7 cm heating element)	
Active Electrode	Monopolar or Bipolar	Bipolar		Bipolar
	Length of Use	Single Use/ Disposable		Single Use/ Disposable
	Diameters	7Fr		7Fr
	Insertable Lengths	65cm or 90cm		60 cm or 100 cm
	Heating element Lengths	3cm or 7cm		3cm or 7cm
	Handle,	Integral to Catheter		Integral to Catheter

	Cable & Connector			
	Materials	STS 304		Unknown
Accessory	Foot switch	Yes	No	
	Cooling Pump	Yes	No	

The predicate device and the VVR Generator System have similar design characteristics and technical specifications.

The difference between the two devices is that the Predicate device delivers RF power output to the catheter electrode, heats the electrode to a constant temperature of 120 degrees for 20s to coagulate the blood vessel, while the Venistar mode of the VVR Generator system controls power output by monitoring the impedance of the vascular tissue during the application. Ex vivo testing, animal studies and clinical evidence (RWD) have demonstrated that the two devices have similar performance characteristics and similar performance effects.

7. SUMMARY OF NON-CLINICAL DATA

Non-clinical tests were conducted to verify that the subject device met all design specifications as was substantially equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

Sterilization and Shelf life

The subject device is supplied sterile and has a shelf life of 3 years from the date of manufacture. A sterilization assurance level of 10⁻⁶ is guaranteed through the EO gas sterilization process, and it has been verified according to the following standards.

- AAMI TIR28: 2016
- ISO 11135:2014
- ISO 11138-1:2017
- ISO 11138-2:2017
- ISO 11737-1:2018
- ISO 11737-2:2009
- ISO 11607-1:2009
- ISO 11607-2:2006
- ISO 10993-7:2008

Biocompatibility

The subject device has a limited contact characteristic of less than 24 hours within blood vessels and complies with the following standards.

- ISO 10993-1:2018
- ISO 10993-4:2017
- ISO 10993-5:2009
- ISO 10993-10:2010
- ISO 10993-11:2017

Electromagnetic Compatibility and Electrical Safety

The Subject device is an active device and complies with the following general and particular standards.

- ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012
- IEC 60601-1-2:2014
- IEC 60601-1-6:2013
- IEC 60601-2-2:2017

Performance Testing – Bench

In order to verify the design characteristics of the subject device as specified in the comparison table, bench

testing was performed in accordance with the FDA guidance "Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery" and "Premarket Notification [510(k)] Submissions for Bipolar Electrosurgical Vessel Sealers for General Surgery", including the test items below.

- Thermal Effects on Tissue

A comparative evaluation of the thermal effect area of the VVR Generator System and the predicate device was performed. The evaluation was performed on coagulation in typical modes for liver, kidney and muscle tissue using electrodes of the same size from both devices. As a result of the test, the devices had similar heat damage area sizes and there was no significant difference.

- Power Output Versus Impedance

The output of the VVR generator system was tested to verify that the output characteristics varied with impedance. The test results verified that the power output decreased as the impedance increased, which is in the intended design output of the VVR Generator System.

10. SUMMARY OF ANIMAL AND CLINICAL DATA

- Animal Study

Animal testing was conducted to verify the effectiveness and safety of the subject device compared to a 510 (k) cleared device in a dog model.

Seven dogs underwent ablation using the control device (ClosureFAST and RFG2) and the subject device (VENISTAR and VVR Generator), Ltd.) in the femoral and cephalic veins. The ablated vein was evaluated macroscopically (2,3,5-triphenyltetrazolium chloride stain, TTC), microscopically (hematoxylin and eosin stain) and ultrasonographic ally. The veins of 1 dog were evaluated on the day of ablation, while the ablated veins of the remaining 6 dogs were evaluated 2 weeks later.

A total of 23 veins (control: 11 veins; subject: 12 veins) were ablated in 7 dogs. Non-TTC stained vein wall areas were identified in all ablated veins. No significant difference was observed in mean vein injury and mean vein wall thickness between the control and experimental devices. There was no blood flow in all veins ablated with the VS, whereas there was residual blood flow in 1 vein ablated with the control device.

The control and subject devices appear to provide similar occlusion rates and degrees of vein wall damage without perivenous side effects.

- Clinical Study.

To support the equivalence of the VVR Generator System, a clinical study that evaluated the safety and effectiveness of the subject device were referenced.

A total of 60 patients (41 males and 19 females) with varicose veins treated with the VVR Generator System were treated in this study, including 79 cases of the great saphenous vein and 10 cases of the small saphenous vein. The mean follow-up was 190±130 days and the success rate of treatment with the VVR generator system was 97.7%. Complications included 20 cases of bruising, 3 cases of phlebitis, 2 cases of recanalization and 1 case of neovascularization. The VVR Generator System was effective and safe for the treatment of varicose veins.

11. CONCLUSION

A comparison of the technical characteristics of the VVR Generator System and the Predicate Device shows that they are very similar in design characteristics and technical specifications. Non-clinical tests per FDA recognized international standards and the FDA guidance on Electrosurgical Devices for General Surgery, animal studies and clinical evidence (RWD) support that the target device conforms to the recognized standard and is substantially equivalent to the predicate device for the intended use.

Therefore, VVR Generator System have been demonstrated to be equivalent to predicate devices.