DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 9, 2016

Venclose, Inc.
% Ms. Pamela Buckman
Pamela M. Buckman, MSN
2800 Pleasant Hill Road, Suite 175
Pleasant Hill, California 94523

Re: K160754
Trade/Device Name: Venclose™ Radiofrequency System (digiRF Generator, EVSRF Catheter)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: August 8, 2016
Received: August 11, 2016

Dear Ms. Buckman:

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 (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. 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.

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); good manufacturing practice requirements as set forth

in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Christopher J. Ronk -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160754

Device Name
Venclose Radiofrequency System

Indications for Use *(Describe)*
The Venclose™ Radiofrequency System (Generator and Catheters) is intended for use in endovascular coagulation of blood vessels 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.

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

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510(K) SUMMARY

K Number: K160754

General Information

Date Prepared: September 8, 2016
Proprietary Name: Venclose™ RF Generator and Catheter System
Common Name: Electrosurgical, Cutting & Coagulation & Accessories
Classification Name and Reference:
Electrosurgical cutting and coagulation device and accessories
21 CFR §878.4400
Regulatory Class: Class II
FDA Panel: General and Plastic Surgery
Product Code: GEI

Applicant: Venclose™, Inc.
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Indication for Use:
The Venclose™ Radiofrequency System (Generator and Catheters) is intended for use in endovascular coagulation of blood vessels in patients with superficial vein reflux.

Predicate Device(s):
The Venclose™ Radiofrequency System is substantially equivalent to the following predicate devices.

K040638	VNUS RF Generator
K061373	VNUS ClosureFast Catheter

Device Description:

The Venclose RF System is composed of two basic components: an energy console or generator (digiRF) and catheters (EVSRF) designed specifically to be used with the generator. The Venclose RF System uses resistive radiofrequency ablation via energy delivery to heat the wall of an incompetent vein with temperature-controlled RF energy to cause irreversible luminal occlusion, followed by fibrosis and ultimately resorption of the vein. The blood then naturally reroutes to healthy veins.

The technique involves percutaneous access and insertion of the EVSRF Catheter into the great saphenous vein (GSV) or other superficial vein under ultrasound guidance, injection of local anesthesia, and thermal energy from a radiofrequency generator (digiRF) applied into the target vein. As the EVSRF Catheter is withdrawn stepwise down the treated length of the vein, thermal damage is inflicted upon the venous endothelium and through the vein wall, resulting in contraction and ultimately destruction of the vessel. The procedure can be performed in an outpatient setting, without the need for general anesthesia, allowing for a walk-in/walk-out procedure with minimal postoperative recovery time.

Materials:

Materials for use in the console are consistent with industry practice for durable cases containing electronic elements. The console is supplied in a non-sterile condition and is not intended to be in contact with the surgical field or the patient. The catheters are made of industry-typical, biocompatible, non-pyrogenic materials and are provided packaged in a sterile condition. They are intended for use in a sterile surgical environment and will make contact with the patient. Biocompatibility data demonstrates that the catheters are in compliance with ISO 10993.

Comparative Summary of Technological Characteristics:

The materials, design, energy source, software integration, sterility methods (EVSRF Catheter component only), environment of use and clinical applications for the Venclose™ Radiofrequency System are comparable to those identified for the predicate devices.

COMPARISON ITEMS	VNUS RF Generator K040638	VNUS Closurefast™ Catheter K061373	SUBJECT DEVICE K160754
Instrument Cable	Attached to catheter, connects to generator, eight feet long		Attached to catheter, connects to generator, eight feet long
Energy/ Frequency	Bipolar 460.8 kHz, max 90 Volts		Bipolar 460 kHz, max 24 Volts
Software	Software Controlled		Software Controlled
Maximum Output Power	6 W/cm (40 W into catheter 7 cm heating element)		6 W/cm (60 W into catheter when heating 10 cm heating element)
Temperature functional limits	10°C to 130°C		10°C to 130°C
Input Voltage	100/240 VAC 50-60 Hz		100/240 VAC 50-60 Hz
Touch Screen	None		Included 7in touchscreen
Weight	20 lbs max		10 lbs max
Dimensions	38 cm x 38 cm x 19 cm (15 in x 15 in x 7.5 in)		23 cm x 25 cm x 17 cm (9 in x 10 in x 7 in)
Mode of Action	Delivers heat to resistive element within the catheter component		Delivers heat to resistive element within the catheter component
Foot Pedal	Not available		Optional
Length of Use		Single Use/Disposable	Single Use/Disposable
Catheters			
Diameters		7F (2.3mm)	6F (2.0 mm)
Insertable Lengths		60 cm or 100 cm	60 cm or 100 cm
Heating element Lengths		7cm (predicate K061373) or separate catheter with 3cm (reference K111887)	Single, adjustable, 10 cm (default) or 2.5 cm
Handle, Cable & Connector		Integral to Catheter	Integral to Catheter
Heating Set Temperature Range		95-120°C – User Select, default at 120°C	120°C, non-adjustable

Non-Clinical Testing:
Device testing was conducted to evaluate conformance to product specifications and applicable standards.

Bench testing included but not limited to the following tests: Catheter Simulation Test, Temperature Test, Pressure Test, Tensile Test, Fluid Test.

Applicable Standards and Guidances are as follows:

- Guidance on Premarket Notification [510(k)] Submissions for Short-Term and Long-Term Intravascular Catheters, March 16, 1995.
- ISO 10555-1:2013 Sterile, Single-Use Intravascular Catheters, Part 1: General Requirements
- EN ISO 13485:2012 Medical devices. Quality management systems. Requirements for regulatory purposes
- EN ISO 14971:2012 Medical devices. Application of risk management to medical devices
- IEC 62304:2006 Medical device software. Software life cycle processes
- IEC 62366:2008 Medical devices. Application of usability engineering to medical devices
- IEC 60601-1:2005 Medical electrical equipment Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-6:2010 Medical electrical equipment Part 1-6: General requirements for safety - Collateral Standard: Usability

Pre-clinical testing:
Animal testing was conducted in a model previously used for research in endovenous ablation for similar devices. The chosen model provided great saphenous and common jugular veins that are sized similarly to human veins. The purpose of the study was to demonstrate proper functionality of the Venclose System in a pre-clinical environment. Objectives included insertion of the catheter though a sheath into the vein, navigation to the intended treatment site, ability to reach a predetermined treatment temperature within a specified time frame and then to hold that temperature for the remainder of the treatment cycle, and capability of reducing the diameter of the vein by an amount similar to that done with the predicate device. All of the objectives were met resulting in a satisfactory study conclusion.

Rationale for Substantial Equivalence
Conclusions drawn from the non-clinical bench and animal testing demonstrate that the Venclose System is as safe, as effective and performs at least as safely and as effectively as the legally marketed devices (K040638 and K061373) for the requested intended use as identified in this Summary.