August 3, 2021

Venclose, Inc.
Ms. Mai-Ly Wilcox, BS, RAC
Sr. Director, Regulatory and Clinical Affairs
2570 N. First Street, Second Floor, #221
San Jose, California 95131

Re: K211806
Trade/Device Name: Venclose Maven System (digiRF Generator and Maven Catheter)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: June 10, 2021
Received: June 11, 2021

Dear Ms. Wilcox:

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. 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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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,

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)*
K211806

Device Name
Venclose Maven System (digiRF Generator and Maven Catheter)

Indications for Use *(Describe)*
The Venclose Maven System (digiRF Generator and Maven Catheter) is intended for endovascular coagulation of blood vessels in patients with perforator and tributary 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

I. SUBMITTER

Venclose, Inc.
2570 N. First Street
2nd Floor, #221
San Jose, CA 95131

Phone: 844-834-6292

Contact Person: Ms. Mai-Ly Wilcox, BS

Date Prepared: August 2, 2021

II. DEVICE

Device Name:	Venclose Maven System (digiRF Generator and Maven Catheter)
Common or Usual Name:	Electrosurgical Cutting and Coagulating Instrument
Classification Name:	Electrosurgical cutting and coagulation device and accessories (21 CFR § 878.4400)
Regulatory Class:	II
Product Code	GEI

III. PREDICATE DEVICES

Primary Predicate Device:	VNUS RFS and RFSFlex Catheters
Primary Predicate Device 510(k) No.:	K052003
Primary Predicate Classification Name:	Electrosurgical cutting and coagulation device and accessories (21 CFR § 878.4400)
Primary Predicate Regulatory Class:	II
Primary Predicate Product Code:	GEI
Secondary Predicate Device:	Venclose digiRF Generator & EVSRF Catheters
Secondary Predicate Device 510(k) No.:	K160754
Secondary Predicate Device Classification Name:	Electrosurgical cutting and coagulation device and accessories (21 CFR § 878.4400)
Secondary Predicate Regulatory Class:	II
Secondary Predicate Product Code:	GEI

IV. DEVICE DESCRIPTION

Venclose Maven System consists of two (2) main components:

1) Maven Catheter with integrated cable connector and,
2) digiRF Generator which delivers radiofrequency (RF) energy to the Maven catheter.

The Maven catheter is a sterile single-use disposable medical device for endovenous radiofrequency ablation. The primary components of the catheter include the shaft, handle and integrated connector cable. The catheter shaft is 6 French (6F = 2.0 mm in diameter) in profile, with an insertable length of 40 cm and a 0.5 cm heating coil. The catheter is energized by the digiRF Generator which is a multi-voltage energy delivery system with touchscreen control that automatically sets the non-adjustable treatment parameters for the catheter.

The Venclose Maven System (digiRF Generator and Maven Catheter) uses resistive radiofrequency ablation (via energy delivered to heat the wall of an incompetent vein) with temperature-controlled RF energy, and an already widely accepted procedure to cause irreversible luminal occlusion. This is followed by fibrosis and ultimately resorption of the vein.

The Venclose Maven System (digiRF Generator and Maven Catheter) supports an optional foot pedal.

V. INDICATIONS FOR USE:

The Venclose Maven System (digiRF Generator and Maven Catheter) is intended for endovascular coagulation of blood vessels in patients with perforator and tributary vein reflux.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

The technology and design features of the subject device are equivalent to the primary predicate device. Specifically, the underlying principle for both devices is to utilize RF based thermal energy to denature collagen and shrink/occlude venous vasculature safely and effectively.

At a high level, the subject and the primary predicate devices are based on the following same technological characteristics:

- Catheter Diameter
- Insertable Length
- Heating Element Length
- Catheter Structure
- Handle, Cable & Connector
- Visualization

The following technological differences exist between the subject and the primary predicate devices:

- Heating Set Temperature Range
- Heating Method
- Treatment Time

The subject device is only a slight modification to the secondary predicate device (predecessor), EVSRF system. The subject device uses the same device components as the EVSRF system. The only differences in technological characteristics between the subject and the secondary predicate devices are the following:

- Insertable Lengths
- Heating Element Lengths
- Heating Set Temperature Range

VII. PERFORMANCE DATA

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

Biocompatibility

The Venclose Maven Catheter is manufactured using identical materials and is processed by similar manufacturing methods as the predecessor device, EVSRF Catheter. Therefore, the biocompatibility data for the EVSRF Catheter was adopted for the Maven Catheter. The biocompatibility testing was conducted in accordance with FDA guidance document "Use of International Standard ISO 10993-1, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process" issued on June 16, 2016, and the International Standard ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a risk management process" as recognized by FDA. The battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation
- Systemic Toxicity
- Hemocompatibility
- Pyrogen Testing

The subject device is considered to be an external communicating device in circulating blood with limited contact duration (≤ 24 hours).

Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety and EMC testing were conducted for the Venclose Maven System (digiRF Generator and Maven Catheter). The system complies with the following standards:

- IEC 60601-1:2012, 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 60601-1-6:2013, Medical electrical equipment - Part 1-6: General requirements for safety - Collateral Standard: Usability including IEC 62366: Application of usability engineering to medical devices

Software Verification and Validation Testing

Software verification and validation testing were conducted, and documentation was provided as recommended by FDA guidance document dated May 11, 2005: "Guidance for the Content of Premarket Submissions for Software Contained Medical Devices".

Non-Clinical

Device testing was conducted to evaluate conformance to product specifications. Bench testing included but are not limited to the following tests: Fluid Ingress Test, Battery Test, Ablation Cycle Test, Temperature Accuracy Test, Tensile Test.

Clinical

An IDE prospective, literature controlled, confirmatory, single-clinic, single-investigator, non-randomized study of the Venclose Maven System (digiRF Generator and Maven Catheter) to treat incompetent perforator veins (IPVs) was performed. The primary objective of the study was to confirm that the Maven device can be used as intended and can treat incompetent perforator veins without significant adverse outcomes related to the use of the device. The study enrolled 27 subjects. Based on the data, the Venclose Maven System (digiRF Generator and Maven Catheter) is safe and effective for treatment of incompetent perforator veins. In addition, the occlusion rate achieved was 80% and the reflux free rate achieved was 93% at the 30-day follow-up.

VIII. CONCLUSION

The conclusions drawn from the non-clinical performance tests and the clinical study demonstrate that the Venclose Maven System is as safe, as effective and performs as well as the Predicate Devices.