August 19, 2025

Venclose, Inc.
Kulveen Dhatt
Senior Manager, Regulatory Affairs
2570 N. First Street
2nd floor #221
San Jose, California 95131

Re: K252316
Trade/Device Name: Venclose digiRF Generator (VCRFG1); Venclose EVSRF Catheter (VC10A256F60, VC10A256F100)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: July 24, 2025
Received: July 25, 2025

Dear Kulveen Dhatt:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

JAMES H. JANG -S

Digitally signed by JAMES H. JANG -S
Date: 2025.08.19 23:28:40 -04'00'

James Jang, Ph.D.
Acting 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252316

Please provide the device trade name(s).

Venclose digiRF Generator (VCRFG1);
Venclose EVSRF Catheter (VC10A256F60, VC10A256F100)

Please provide your Indications for Use below.

The Venclose System (Venclose digiRF Generator with EVSRF Catheter) is intended for endovascular coagulation of blood vessels in patients with superficial vein reflux.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

21 CFR 807.92

As required by the Safe Medical Devices Act of 1990, coded under Section 513, Part (I)(3)(A) of the Food, Drug and Cosmetic Act, a summary of the information upon which substantial equivalence determination is based is as follows:

1. Submitter Information:

Applicant:	Venclose, Inc. 2570 N. 1st Street, Floor 2, #221 San Jose, CA 95131
Phone:	602-830-5365
Contact:	Kulveen Dhatt, Senior Regulatory Affairs Manager
Date:	July 24, 2025

2. Subject Device:

Device Trade Name:	Venclose™ digiRF Generator
Classification Name:	Electrosurgical, Cutting & Coagulation & Accessories (Product Code GEI)
Review Panel:	General & Plastic Surgery
Regulation Number:	21 CFR 878.4400

3. Predicate Devices:

Venclose™ Radiofrequency System (digiRF Generator, Venclose™ EVSRF Catheter)

K160754; cleared September 9, 2016

Venclose™ digiRF Generator, K250068, cleared February 4, 2025

4. Device Description:

The Venclose™ digiRF Generator is a multi-voltage energy delivery system with touchscreen control that automatically sets the non-adjustable treatment parameters for the catheter to be used with the generator (time, temperature, etc.), which is connected via a triaxial catheter connector port. The Venclose™ digiRF Generator is intended to be used with Venclose™ RF Catheter(s) (either the Venclose™ EVSRF Catheter or the Venclose™ Maven Catheter) as a system. 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 scope of this 510(k) is only the Venclose™ digiRF Generator as the generator software has been modified. The Venclose™ Maven Catheter is not in the scope of this submission as the changes discussed within this submission are only applicable to the Venclose™ digiRF Generator as used with the Venclose™ EVSRF Catheter. There is no change to the Venclose™ EVSRF Catheter, as previously cleared via K160754.

5. Indications for Use of Device:

The Venclose™ System (Venclose™ digiRF Generator with EVSRF Catheter) is intended for endovascular coagulation of blood vessels in patients with superficial vein reflux.

6. Technological Comparison to Predicate Devices:

The scope of this 510(k) is only the Venclose™ digiRF Generator as the generator software has been modified. There is no change to the Venclose™ EVSRF Catheter, as previously cleared via K160754.

The technological characteristics of the subject device are substantially equivalent to those of the predicate devices, in terms of following:

- Intended Use
- Indications for Use
- Performance Characteristics
- Target Population
- Fundamental Scientific Technology
- Operating Principle (Mode of Action)
- Packaging Configuration

The subject device and the predicate devices are different in the following manner:

- Software Modification

7. Performance Testing Summary:

To demonstrate substantial equivalence of the subject device to the predicate devices, the technological characteristics and performance criteria were evaluated. Using the FDA Guidance document, “Design Control Guidance for Medical Device Manufacturers,” dated March 11, 1997, and internal risk assessments procedures, the following non-clinical tests were performed:

- Software Verification and Validation

The results demonstrate that the technological characteristics and performance criteria of the modified Venclose™ digiRF Generator is comparable to the predicate devices and that it performs as safely and as effectively as the legally marketed predicate devices.

8. Conclusion:

The modified Venclose™ digiRF Generator is substantially equivalent to the legally marketed predicate devices, Venclose™ Radiofrequency System (digiRF Generator, Venclose™ EVSRF Catheter; K160754) and Venclose™ digiRF Generator; K250068).