October 22, 2019

Vein360, LLC
Suzanne Meyer
CEO
4460 Lake Forest Drive, Suite 230
Blue Ash, Ohio 45242-3741

Re: K191073
Trade/Device Name: Vein360 Endovenous Radiofrequency Ablation (RFA) Catheter
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories, Reprocessed
Regulatory Class: Class II
Product Code: NUJ
Dated: April 17, 2019
Received: April 22, 2019

Dear Suzanne Meyer:

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

Reprocessed Single-Use Device Models Subject to Clearance:

OEM Model Number	Device Name/Description	Original Manufacturer	Reprocessed Model Number
CF7-3-60	Covidien™ Closure*FAST*™ Radiofrequency Catheter (3cm heating length, 60cm insertable length)	Covidien	VEN-3-60
CF7-7-60	VNUS® Closure*FAST*™ Catheter (7cm heating length, 60cm insertable length)	VNUS Medical Technologies, Inc.	VEN-7-60
CF7-7-100	VNUS® Closure*FAST*™ Catheter (7cm heating length, 100cm insertable length)	VNUS Medical Technologies, Inc.	VEN-7-100

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K191073

Device Name

Vein360 Endovenous Radiofrequency Ablation (RFA) Catheter

Indications for Use *(Describe)*

The Vein360 Endovenous Radiofrequency Ablation (RFA) Catheter is intended for 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.

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SECTION 5: 510(k) SUMMARY

Date of Preparation: April 17, 2019 (revised October 22, 2019)

Company Name / Contact:

Company: Vein360, LLC
4460 Lake Forest Drive
Suite 230
Blue Ash, OH 45242

Contact: Suzanne Meyer
CEO
Phone: (513) 554-1300

Device Identification:

Proprietary Name:	Vein360 Endovenous Radiofrequency Ablation (RFA) Catheter
Common Name:	Electrosurgical Device
Classification Name:	Electrosurgical Cutting and Coagulation Device and Accessories, Reprocessed
Classification Reference:	21 CFR § 878.4400
Classification Panel:	79 – General & Plastic Surgery
Device Product Code:	NUJ
Proposed Regulatory Class:	Class II

Device Description:

The Vein360 Endovenous RFA Catheter is a reprocessed single-use device (SUD) consisting of a molded handle with actuation switch, an integrated instrument cable, and a flexible catheter shaft with a radiofrequency (RF) heating element at the distal end. The catheter and integrated connection cable are provided sterile and meant for single patient use. The catheter's function is to provide thermal energy to the desired treatment site via RF heating of the heating element and to relay temperature back to the RF generator.

The Vein360 Endovenous RFA Catheter is subjected to reprocessing

operations following the initial clinical use of the OEM predicate. These operations include cleaning, inspection, packaging and sterilization. After reprocessing, the Vein360 reprocessed Endovenous RFA Catheter retains substantially equivalent performance to that of the OEM predicate. The Vein360 reprocessed Endovenous RFA Catheter is reprocessed one (1) time.

Indications for Use:

The Vein360 Endovenous RFA Catheter is intended for endovascular coagulation of blood vessels in patients with superficial vein reflux.

Substantial Equivalence Information:

The Vein360 Endovenous RFA Catheter is a reprocessed SUD that is substantially equivalent to the new, unused device of the same product currently marketed by the device's original equipment manufacturer (OEM) and described herein with respect to indications for use, device design, materials, performance and method of sterilization. As a reprocessed SUD, there are no changes to the clinical applications, patient population, or method of operation. Within the proposed class, the following OEM devices are used as a predicate device for comparison: VNUS® Closure*FAST*™ Catheters (K061373) Models CF7-7-60 and CF7-7-100, and Covidien™ Closure*FAST*™ Radiofrequency Catheter (K111887) Model CF7-3-60. The following table summarizes the Vein360 reprocessed Endovenous RFA Catheters vs. the predicate OEM devices:

Table 1. OEM vs. Vein360 Models

OEM Model Number	OEM Name	Predicate 510(k)	Device Name/Description	Vein360 Model Number
CF7-3-60	Covidien	K111887	Covidien™ Closure*FAST*™ Radiofrequency Catheter (3cm heating length, 60cm insertable length)	VEN-3-60
CF7-7-60	VNUS Medical Technologies, Inc.	K061373	VNUS® Closure*FAST*™ Catheter (7cm heating length, 60cm insertable length)	VEN-7-60
CF7-7-100	VNUS Medical Technologies, Inc.	K061373	VNUS® Closure*FAST*™ Catheter (7cm heating length, 100cm insertable length)	VEN-7-100

Performance Data:

Results of performance testing demonstrate the Vein360 reprocessed Endovenous RFA Catheters are substantially equivalent to the OEM predicate devices and effective for their intended function. Substantial equivalence determination was concluded through successful completion of a battery of testing, which included:

- Cleaning validation per AAMI TIR30:2011/(R)2016

- Sterilization validation per EN ISO 11135:2014
- Biocompatibility per ANSI AAMI ISO 10993
- Pyrogenicity per ANSI AAMI ST72:2011/(R)2016
- Physical and mechanical integrity testing
- Electrical safety testing per IEC 60601
- Comparative ex vivo tissue testing in three (3) tissue types

With respect to SUD reprocessing, comprehensive cleaning validation studies included enumeration of clinical soil levels to establish a worst-case basis for artificial test soil development. Using both clinical and artificial test soils, the cleaning operation was validated with a high degree of confidence by objectively demonstrating removal of all physical soil under minimum operating conditions. The body of this submission includes all data related to the cleaning process and validation.

Electro-mechanical performance testing was performed to demonstrate that the reprocessing operations did not adversely affect the predicate device's form, fit or function. The following list summarizes the extensive scope of performance tests executed to fully demonstrate substantial equivalence of the Vein360 reprocessed Endovenous RFA catheters to their OEM predicate, all of which are detailed within the body of this submission:

- Guide wire testing
- Physical dimensions
- Impact resistance
- Integrity testing
- Thermal accuracy
- Continuity and resistance
- Connector testing
- Leakage current
- Radiated emissions
- RF immunity

Finally, the Vein360 reprocessed Endovenous RFA Catheters were compared to the predicate device in a comprehensive ex vivo study which was performed by an independent laboratory. The study measured ablative performance across three (3) tissue types (muscle, liver and kidney). The Vein360 reprocessed Endovenous RFA Catheters performed in a substantially equivalent manner to their OEM predicates, indicating that the reprocessing of the catheters does not impact ablation performance and that the thermal injury zones between the Vein360 reprocessed Endovenous RFA catheter and the OEM predicate are equivalent.

The totality of data collected through comprehensive performance testing has successfully demonstrated that the Vein360 reprocessed Endovenous RFA Catheters are equivalent to their OEM predicates.