June 6, 2023

Vein 360 LLC
Suzanne Meyer
CEO
4460 Lake Forest Dr Suite 230
Blue Ash, Ohio 45242-3741

Re: K230584
Trade/Device Name: Vein360 Reprocessed Visions PV.035 Digital IVUS Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic intravascular catheter
Regulatory Class: Class II
Product Code: OWQ
Dated: May 11, 2023
Received: May 12, 2023

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,

Aneesh S. Deoras -S

Aneesh Deoras
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

The reprocessed devices included in the scope of the submission are as follows:

Description	Item Number	French Size	Guide Wire	Minimum Sheath	Length (cm)
Vein360 Reprocessed Visions PV .035 Digital IVUS Catheter	88901	7	0.035"-0.038"	8.5 F	90

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)*
K230584

Device Name
Vein360 Reprocessed Visions PV .035 Digital IVUS Catheter

Indications for Use *(Describe)*
The Vein360 Reprocessed Visions PV .035 Digital IVUS Catheter is designed for use in the evaluation of vascular morphology in blood vessels of the peripheral vasculature by providing a cross-sectional image of such vessels. The Vein360 Reprocessed Visions PV .035 Digital IVUS Catheter is designed for use as an adjunct to conventional angiographic procedures to provide an image of the vessel lumen and wall structures and dimensional measurements from the image.

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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Date of Preparation: March 1st, 2023

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 Reprocessed Visions PV .035 Digital IVUS Catheter
Common Name:	Diagnostic Intravascular Catheter
Classification Reference:	21 CFR 870.1200
Classification Panel:	Cardiovascular
Device Product Code:	OWQ
Regulatory Class:	Class II

Predicate Devices:

Predicate Device Trade Name	Reference Number	Predicate 510(k)
Visions® PV .035 Digital IVUS Catheter	88901	K153094

Device Description:

The Vein360 Reprocessed Visions PV .035 Digital IVUS catheter is a reprocessed single use device. After clinical use of the Visions PV .035 Digital IVUS Catheter (Manufactured by Philips), the IVUS catheter is shipped to Vein360 per established Vein360 instructions. Upon receipt, the Visions PV .035 Digital IVUS catheter is cleaned, inspected, functionally tested, hydrophilic coated, packaged and sterilized using ethylene oxide (EO) gas.

The Vein360 Reprocessed Visions PV .035 Digital IVUS catheter is an over-the-wire intravascular imaging catheter containing an ultrasound transducer located at the distal end of the catheter. This transducer utilizes a 64-element cylindrical array that radiates acoustic energy into the surrounding tissue and detects subsequent echoes. The information from the echoes is used to generate real-time images of the peripheral vessels.

The catheter is introduced percutaneously or via surgical cutdown into the peripheral vasculature. The catheter is designed to track over a maximum guidewire of 0.038” (0.97mm).

The catheter is 90cm in working length with 1cm inked markers (non-radiopaque) along the proximal shaft for length assessments during pull back. There are 25 radiopaque markers spaced 1cm apart along the distal shaft for quick length measurements under angiogram imaging. A hydrophilic coating is applied externally to the distal end of the catheter. The Vein360 Reprocessed Visions PV .035 Digital IVUS catheter maintains all mechanical and electrical properties of the predicate device after reprocessing operations.

The Vein360 Reprocessed Visions PV .035 Digital IVUS catheter may only be used with Volcano s5 Series and CORE Series imaging systems.

The Vein360 Reprocessed Visions PV.035 Digital IVUS catheter is not supplied with any accessories.

The Visions PV .035 Digital IVUS catheter can only be reprocessed once. All Vein360 Reprocessed Visions PV .035 Digital IVUS catheters are permanently marked to indicate it has been reprocessed.

The scope of this submission is as follows:

Description	Reference Number	French Size	Guidewire	Minimum Sheath	Working Length
Vein360 Reprocessed Visions PV .035 Digital IVUS Catheter	88901	7	0.035” – 0.038”	8.5 F	90 cm

Indications for Use:
The Vein360 Reprocessed Visions PV .035 Digital IVUS Catheter is designed for use in the evaluation of vascular morphology in blood vessels of the peripheral vasculature by providing a cross-sectional image of such vessels. The Vein360 Reprocessed Visions PV .035 Digital IVUS Catheter is designed for use as an adjunct to conventional angiographic procedures to provide an image of the vessel lumen and wall structures and dimensional measurements from the image.

Substantial Equivalence Information:
The Vein360 Reprocessed Visions PV .035 Digital IVUS catheter 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 intended use, design, materials, performance, and function. As a reprocessed SUD, there are no changes to the clinical applications, patient population, or method of operation.

Vein360 Reprocessed Visions PV .035 Digital IVUS Catheter		
Feature	**Predicate Device**	**Subject Device**
Hydrophilic Coating Length	30cm	Identical
Working Length	90cm	Identical
Working Length Diameter	7.0 F	Identical
Transducer Diameter	8.2 F	Identical
Guidewire Compatibility	0.035" (0.89mm) - 0.038" (0.97mm)	Identical
Sterilization Method	Ethylene Oxide (EO) gas	Identical
Markers	Inked and RO markers spaced 1cm apart along the shaft	Identical
Shelf Life	2 years	13 months
Uses	Single patient use	Identical
Accessories	None	Identical

Performance Data:
With respect to SUD reprocessing, comprehensive cleaning validation studies were performed ensuring Visions PV .035 Digital IVUS catheters were clinically used and then soiled with artificial test soil. 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.

Performance validation studies were performed after ensuring Visions PV .035 Digital IVUS catheters were clinically used and then soiled with artificial test soils. The cleaning process was conducted using maximum operating conditions in order to challenge functional performance of the device. Electro-mechanical performance

testing was performed to demonstrate that the reprocessing operations did not adversely affect the predicate device's form, fit, or function.

Results of performance testing demonstrate the Vein360 Reprocessed Visions PV .035 Digital IVUS catheters are substantially equivalent to the predicate devices which are safe and effective for their intended use. Substantial equivalence determination was concluded through successful completion of bench and laboratory testing, which included:

- Cleaning Validation
- Drying Validation
- Sterilization Validation
- Endotoxin Test Method Validation
- Biocompatibility
- Performance Validation
  - Simulated Use
  - Dimensional Integrity
  - Mechanical integrity
  - Electrical Integrity
  - Electrical Safety
  - Hydrophilic Coating Integrity
  - Acoustic Output
  - Image Quality
  - System Compatibility
- Packaging Validation

The Vein360 Reprocessed Visions PV .035 Digital IVUS catheter is validated for one reprocessing cycle after successful completion of the above performance testing. All Vein360 Reprocessed Visions PV .035 Digital IVUS catheters are permanently marked and tracked via OEM label during reprocessing. Vein360 Reprocessed Visions PV .035 Digital IVUS catheters are taken out of service and rejected from further reprocessing once the maximum number of cycles have been reached. Further, Vein360 restricts its reprocessing to exclude devices previously reprocessed by other reprocessors.

Conclusion:

Vein360 concludes the Vein360 Reprocessed Visions PV .035 Digital IVUS catheter is as safe, as effective, and performs as well as or better than the predicate device.