DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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February 9, 2017

Velano Vascular
Tiffini Diage, MPH
Consulting Director of Regulatory Affairs
1756 Fillmore Street
San Francisco, California 94115

Re: K163508
Trade/Device Name: PIVO™
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood Specimen Collection Device
Regulatory Class: II
Product Code: JKA
Dated: January 11, 2017
Received: January 12, 2017

Dear Ms. Tiffini Diage:

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 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 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,

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental 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)*
K163508

Device Name
PIVO™

Indications for Use *(Describe)*
The PIVO™ device is attached to a peripheral IV catheter for use as a direct blood draw device into a vacuum tube or a syringe.

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: K163508

Submitter:	Velano Vascular 1756 Fillmore St San Francisco CA 94115
Contact Person:	Tiffini Diage Consulting Director Regulatory Affairs Phone: 707.799.6732 E-mail: tdiage@raechelon.com
Trade Name:	PIVO™
Common Name:	Blood specimen collection device
Classification:	Class II
Product Code:	JKA per 21CFR 862.1675
Predicate Device(s):	The subject device is equivalent to the following devices: • K152924 – TIVA
Device Description:	The PIVO™ device is a sterile, single use device. It is a needle- free blood collection device that attaches to a peripheral IV system (PIV). The device is comprised of an inner tube with a pusher/slider, proximal flexible tube with female luer, outer housing and clip-to-connect distal end. The clip-to-connect attaches to the PIV system. The female luer attaches to a blood transfer device or syringe. The device is then advanced to collect a blood sample. Once complete, the device is retracted and removed from the PIV. The device comes in two sizes compatible with 20 and 22 gage PIV's, respectively.
Indication for Use:	The PIVO™ device is attached to a peripheral IV catheter for use as a direct blood draw device into a vacuum tube or a syringe.
Reason For Submission:	Component and material changes were made. The table below identifies the specific changes made.
Technological Characteristics:	The PIVO device attaches to a PIV system via a clip-to-connect attachment. This was previously a twist on attachment. Once attached a pusher / slider (previously was a plunger style) is moved forward and advances the inner tube into the PIV system. The inner tube in the predicate design was PEEK or nylon and has been changed to polyimide for both sizes.

	PIVO (Subject Device)	**TIVA (Predicate Device)**
510(k) Number Decision Date	To be determined	K152924

Manufacturer	Same	Velano Vascular, Inc.
Classification	Class II	Class II
Product Code	JKA	JKA
Regulation	21 CFR 862.1675	21 CFR 862.1675
Indications for Use	Same	The TIVA™ device is attached to a peripheral IV catheter for use as a direct blood draw device into a vacuum tube or a syringe.
Intended Use	Same	Venous blood drawing
Patient Interface	Same	Separately placed commercially available peripheral IV catheter
PIV Attachment	Clip-to-Connect	Male Luer Connection
Blood Collection Attachment	Same	Female Luer to Blood Transfer Device or Syringe
Blood Control Mechanism	Same	Cap on female luer and clamp on flexible tubing
Materials		
Tubing Proximal	Same	Pebax Transparent Flexible
Tubing Distal	Polyimide (20G & 22G)	PEEK (22G) Nylon (20G)
Performance Specifications		
Compatible PIV Sizes	Same	14G – 22G
Inner Tubing Length	5.85”	4.99”
Outer Diameter (OD) of Tubing	20G = 0.0275” 22G = 0.0210”	20G = 0.0275” 22G = 0.0215”
Inner Diameter (ID) of Tubing	20G = 0.0205” 22G = 0.0156”	20G = 0.0220” 22G = 0.0180”
Sample collection	Same	Device attaches to female luer of PIV system, tube inserted into PIV, blood is drawn through tube into a blood transfer device
Complete Retraction	Same	Yes
Sterilization Method	Same	Gamma
Single Use Only	Same	Yes

Performance Testing:	Based on the identified risks additional testing was performed. As a result of verification and validation activities and risk assessment, testing ensured the device design meets its functional and performance requirements. The following tests were performed: • Clamp functional testing • Leak testing • Dimensional testing • Joint strength testing • Performance testing • Flow rate testing • Biocompatibility testing per ISO 10993-1 ▪ ISO 10993-4 ▪ ISO 10993-5 ▪ ISO 10993-10 ▪ ISO 10993-11
Summary of Substantial Equivalence:	The changes made to the previously cleared TIVA (now called PIVO™) device does not raise new questions regarding safety and efficacy of the device. PIVO is equivalent to the predicate device. This conclusion is based upon the devices' identical indications for use, principles of operation, fundamental scientific technology, and performance specifications. The changes made were tested using the same acceptance criteria as the predicate device and provide objective evidence that there are no new risks and the device is substantially equivalent.