January 21, 2020

Velano Vascular
Tiffini Wittwer
Consulting Director Regulatory Affairs
221 Pine St #200
San Francisco, California 94104

Re: K193569
Trade/Device Name: PIVO™
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood Specimen Collection Device
Regulatory Class: Class II
Product Code: JKA
Dated: December 17, 2019
Received: December 23, 2019

Dear Tiffini Wittwer:

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,

for Geeta Pamidimukkala
Acting Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of Gastrorenal, ObGyn,
General Hospital and Urology 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193569

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary (K193569):

Submitter:	Velano Vascular 221 Pine St #200 San Francisco CA 94104
Date prepared:	January 6, 2020
Contact Person:	Tiffini Wittwer, MPH Consulting Director Regulatory Affairs Phone: 707.799.6732 E-mail: twittwer@mededge.io
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: • K190604 – PIVO™
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 (PIV) catheter system. 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 inner tube is then advanced to collect a blood sample. Once complete, the inner tube is retracted, and the device is removed from the PIV. The device is available in three sizes, 20, 22, and 24 gauge.
Indications for Use:	The PIVO™ device attaches to a peripheral IV catheter system for use as a direct blood draw device into a vacuum tube or a syringe.
Reason For Submission:	An alternate colorant material is being added to the pink components of the 20G device. Additional changes since last 510(k) clearance include the addition of a second contract manufacturer and alternate packaging material for all products.
Technological Characteristics:	The PIVO™ device attaches to a PIV system via a clip-to-connect attachment. Once attached, a slider is moved forward and advances the inner tube into the PIV system. The differences between the predicate and the subject devices, are the alternate red colorant for the 20G components and the addition of a nylon/ nylon pouch for packaging and terminally sterilizing the devices.

	PIVO Devices (Subject Device)	PIVO Devices (Predicate Device)	Analysis of Differences
510(k) Number Decision Date	K193569	K190604	
Manufacturer	Same	Velano Vascular, Inc.	
Classification	Same	Class II	
Product Code	Same	JKA	
Regulation	Same	21 CFR 862.1675	
Indications for Use	Same	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.	
Intended Use	Same	Venous blood drawing	
Patient Interface	Same	Separately placed commercially available peripheral IV catheter	
PIV Attachment	Same	Clip-to-Connect	
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	
Tubing	Same Same	Transparent Flexible	
Compatible PIV Sizes	Same	14G – 24G	
Color	20G Pink DEV-MCC 0436 OR DEV-MCC 0155 Same Same	20G Pink DEV-MCC 0155 22G Blue DEV-MMC 0154 24 G Yellow DEV-MCC 0267	Biocompatibility assessment and testing demonstrate that this alternate material does alter the safety of the device
Inner Tubing Length	Same	141.2mm	

Outer Diameter (OD) of Distal Inner Tubing	Same	20 gauge = 0.709mm max 22 gauge = 0.543mm max 24 gauge = 0.400mm max	
Wall Thickness of Distal Inner Tubing	Same	20 G wall = 0.0750mm +/- 0.01mm 22 G wall = 0.0635mm +/- 0.01mm 24 G wall = 0.0575mm +/- 0.01mm	
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	
Packaging Material	Tyvek/PET OR Nylon/Nylon	Tyvek/PET	Transit, Aging, and Packaging validation testing demonstrates that the difference does not alter the safety of the devices
Complete Retraction	Same	Yes	
Sterilization Method	Same	Gamma	
Single Use Only	Same	Yes	

Risk Analysis:	A risk analysis was performed for the modifications done to the subject device, in accordance to ISO 14971, Medical Devices – Applications of Risk Management to Medical Devices and Velano Vascular Risk Management SOP. Possible risks were identified which resulted from the alternate materials and new contract manufacturer. Based on risk identification, verification and validation activities were carried out to ensure the risk acceptability criteria have been met and the risks have been mitigated. All testing was performed on sterilized product.
Performance Testing:	Based on the risks identified, the following tests were performed on the PIVO devices: • Leak testing • Dimensional testing • Joint strength testing • Flow rate testing

	• Packaging testing per ASTM D4169-16 Standard Practice For Performance Testing Of Shipping Containers And Systems, ASTM F1980-16 Standard Guide For Accelerated Aging Of Sterile Barrier Systems For Medical Devices, and ISO 11607-1:2019 Packaging For Terminally Sterilized Medical Devices - Part 1: Requirements For Materials, Sterile Barrier Systems And Packaging Systems • Biocompatibility testing per ISO 10993-1 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process and
Summary of Substantial Equivalence:	The changes made to the previously cleared PIVO™ devices does not raise different questions regarding the safety and effectiveness of the device. Current PIVO™ is substantially equivalent to the predicate PIVO™ devices. This conclusion is based upon the devices' identical intended use, indications for use, principles of operation, fundamental scientific technology, patient contacting materials, and performance specifications. The changes made were tested using the same acceptance criteria as the predicate device and demonstrated that there are no new risks and the device is substantially equivalent.