October 3, 2022

Velano Vascular
Tiffini Wittwer
Regulatory Affairs Consultant
221 Pine Street #200
San Francisco, California 94104

Re: K201237
Trade/Device Name: Velano Vascular Blood Collection Adapter
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood Specimen Collection Device
Regulatory Class: Class II
Product Code: JKA
Dated: September 26, 2022
Received: October 3, 2022

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,

Payal Patel
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)*
K201237

Device Name
Velano Vascular Blood Collection Adapter

Indications for Use *(Describe)*
The Velano Vascular Blood Collection Adapter is indicated for use as a blood collection system that manually diverts the initial specimen prior to collection of a subsequent test sample to reduce the frequency of blood culture contamination when contaminants are present in the initial blood sample compared to blood cultures drawn with standard procedure without manual diversion.

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 K201237 – September 26, 2022

510(k) Summary

Submitter:	Velano Vascular 221 Pine Street #200 San Francisco CA 94104
Contact Person:	Tiffini Wittwer Regulatory Affairs Consultant Phone: (707) 799-6732 Email: twittwer@mededge.io
Trade Name:	Velano Vascular Blood Collection Adapter
Common Name:	Blood Collection Serum Separators, Systems, Vials, Tubes
Classification:	Class II
Product Code:	JKA
Regulation:	CFR 862.1675 – Blood specimen collection device
Predicate Device(s):	The subject device is equivalent to the following device: • Magnolia Steripath Gen2 Blood Collection System - K192247
Device Description:	The Blood Collection Adapter is a sterile, single-use device that removes the initial portion of the blood specimen (potentially contaminated) into a waste or discard tube prior to collecting a subsequent blood sample. The Blood Collection Adapter is comprised of a transfer device, a waste tube, a skirt that holds the waste tube in place, and an adapter inside the transfer device that is used for narrow neck culture tubes and additional blood collection tubes. The device is designed to be attached to a newly placed IV-line, vascular access device, or venipuncture needle set and is not intended for blood specimen collection from preexisting lines or IV site. Place a new peripheral IV catheter prior to drawing blood sample. The device collects approximately 3mL of the initial blood sample into the waste tube. The subsequent blood sample is collected directly into a culture bottle (not provided by Velano Vascular) or into an evacuated tube for additional processing.
Indication for Use:	The Velano Vascular Blood Collection Adapter is indicated for use as a blood collection system that manually diverts the initial specimen prior to collection of a subsequent test sample to reduce the frequency of blood culture contamination when contaminants are present in the initial blood sample compared to blood cultures drawn with standard procedure without manual diversion.

	Subject Device: Velano Vascular Blood Collection Adapter	**Predicate Device: Magnolia Steripath® Gen2 Blood Collection System**	**Comment:**
510(k)	K201237	K192247	
Manufacturer	Velano Vascular	Magnolia	
Classification	II	II	Same
Product Code	JKA	JKA	Same
Subsequent Product Code	None	FPA	Predicate design allows for infusion, subject device does not. No effect on safety or efficacy for blood collection indication
Regulation	862.1675	862.1675	Same
Common Name	Blood Specimen Collection Set	Blood Specimen Collection Set	Same
Device Classification	Tubes, Vials, Systems, Serum Separators	Tubes, Vials, Systems, Serum Separators	
Indications for Use	The Velano Vascular Blood Collection Adapter is indicated for use as a blood collection system that manually diverts the initial specimen prior to collection of a subsequent test sample to reduce the frequency of blood culture contamination when contaminants are present in the initial blood sample compared to blood cultures drawn with standard procedure without manual diversion.	The Steripath® Gen2 Blood Collection System is indicated for use as a blood collection system that diverts and sequesters the initial specimen prior to collection of a subsequent test sample to reduce the frequency of blood culture contamination when contaminants are present in the initial blood sample compared to blood cultures drawn with standard procedure without manual diversion. Additionally, components of the system may be used for infusion following sample collection after disconnection of the Initial Specimen Diversion Device® (ISDD®). Venipuncture needles are indicated for short term infusion (less than 2 hours).	Same indication for use for blood collection; subject device does not have an infusion indication.
Intended Use	The Velano Vascular Blood Collection Device is intended	The Steripath® Gen2 Blood Collection System is a system to draw blood	Same

	Subject Device: Velano Vascular Blood Collection Adapter	**Predicate Device: Magnolia Steripath® Gen2 Blood Collection System**	**Comment:**
	to draw blood for in vitro diagnostic testing.	for in vitro diagnostic testing.	
Method of Operation	Used with newly placed IV lines or blood collection devices, diverts initial blood volume into separate location prior to attaching culture bottle	Used with newly placed IV lines or blood collection devices, , diverts initial blood volume into separate location prior to attaching culture bottle	Same
Patient Contact	Yes	Yes	Same
Blood Volume Discarded	2 – 3mL	1.5 – 2mL	Subject device diverts more blood than predicate. Simulated use and contamination study demonstrate this difference does not alter the safety or efficacy of the device.
Blood collection device inlet	Male Luer	Male Luer	Same
Off the shelf collection device	Yes	Yes	Same
Infusion Capabilities	No	Yes	Subject device has no infusion indication where predicate device does. No change to the safety or efficacy of the device for blood collection
Can be used for additional blood tube draws (after blood culture collection)	No	No	Same
Disposable or Reusable	Single-use, disposable	Yes	Same
Sterilization Method	Ethylene Oxide	Yes	Same
Minimum SAL	1 x 10-6	Yes	Same

Functional and Safety Testing:	To verify that the device design meets its functional and performance requirements, devices underwent physical and mechanical testing. 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: • Visual inspection • Simulated shipping • Dimensional measurements • Activation force • Inlet compatibility • Outlet compatibility • Simulated use • Discard volume • Multiple engagements Testing was performed in accordance with the following: ISO 80369-7, Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications ISO 11135, Sterilization of health-care products -Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices AAMI TIR28, Product Adoption and Process Equivalence for Ethylene Oxide Sterilization ISO 10993-5, Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity ISO 10993-10, Biological evaluation of medical devices – Part 10: Tests for skin sensitization ISO 10993-23, Biological evaluation of medical devices – Part 23: Tests for irritation

	ASTM D4169, Standard practice for performance testing of shipping containers and systems ASTM F1980, Standard guide for accelerated aging of sterile medical device packages. In addition, a contamination study was performed to validate the device performs as intended. Under simulated use conditions, test samples were contaminated with various organisms (*Staphylococcus aureus, Bacillus Cereus, Escherichia coli, Pseudomonas aeruginosa).* Test samples using the Blood Collection Adapter demonstrated no growth and all positive control test samples demonstrated growth of each organisms evaluated.
Conclusion:	The Blood Collection Adapter device is substantially equivalent to the predicate device listed above. This conclusion is based upon the identical intended use, similar indication for use, principles of operation, and sterilization processes and results of functional performance testing and contamination study.