DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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January 8,2015

Velano Vascular
Ms. Tiffini Diage
Consulting Director of Regulatory Affairs
1500 Locust Street, Suite 4311
Philadelphia, PA 19102

Re: K142946
Trade/Device Name: TIVA™
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood Specimen Collection Device
Regulatory Class: II
Product Code: JKA
Dated: October 8, 2014
Received: October 10, 2014

Dear Ms. 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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 yours,

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1.0 Indications for Use Statement

Device Name: TIVA™

Indications for Use:

The TIVA™ device is attached to a peripheral IV catheter at the time of IV catheter placement for use as a direct blood draw device into a vacuum tube or a syringe.

Prescription Use ___X____ (21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

Table 1: 510(k) Summary

Submitter:	Velano Vascular, Inc. 1500 Locust St Suite 4311 Philadelphia PA 19102
Contact Person:	Tiffini Diage Consulting Director Regulatory Affairs Phone: 707.799.6732 E-mail: tdiage@raechelon.com
Date Prepared:	10/10/14
Trade Name:	TIVA™
Common Name:	Blood specimen collection device
Classification:	Class II
Product Code:	21 CFR 862.1675
Predicate Device(s):	The subject device is equivalent to the following devices: • K081229 - Saf-T Closed Blood Collection System
Device Description:	The TIVA™ 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 plunger, proximal flexible tube with female luer, and outer barrel with male luer. The male luer 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 20 and 22 gauge.
Indication for Use:	The TIVA device is attached to a peripheral IV catheter at the time of IV catheter placement for use as a direct blood draw device into a vacuum tube or a syringe.

Functional and Safety Testing:	To verify that the device design meets its functional and performance requirements, representative samples of the device underwent biocompatibility, sterilization, and mechanical testing in accordance with the following industry standards. ISO 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process ISO-11137-1 Sterilization of Health Care Products. GAMMA Sterilization Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices

Table 2: Comparison to Predicate Device

	TIVA (Subject Device)	**Saf-T Closed Blood Collection System (Predicate Device)**
Manufacturer	Velano Vascular, Inc.	Smiths Medical ASD, Inc.
Intended Use	Same	Venous blood sampling
Patient Interface	Same	Separately placed commercially available peripheral IV catheter
PIV Attachment	Same	Male Luer Connection
Blood Collection Attachment	Same	Female Luer to Blood Transfer Device or Syringe
Materials and Chemical Composition		
Tubing	Same	Transparent Flexible
Latex	Same	No
Pyrogen	Same	Non-pyrogenic
Performance / Design Specifications		
Compatible PIV Sizes	14G – 22G	14G – 24G
Tubing Length	11”	6” and 12”
Sample collection	Male luer connection to PIV, tube inserted into PIV, blood is drawn through tube into an blood transfer device	Male luer connection to PIV, blood is drawn through tubing and into blood transfer device
Complete Retraction	Yes	Not Applicable
Sterilization Method	Gamma	Ethylene Oxide
Single Use Only	Same	Yes

Conclusion:	Velano Vascular considers the TIVA device to be equivalent to the predicate device listed above. This conclusion is based upon the device's similarities in indications for use, principles of operation, materials, and intended use.