



Food and Drug Administration
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January 7, 2016

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

Re: K152924
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, 2015
Received: October 9, 2015

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,

 Tina
Kiang -S

for 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

Indications for Use

510(k) Number (if known)

K152924

Device Name

TIVA™

Indications for Use (Describe)

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.

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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K152924--510(k) Summary

Table 1: 510(k) Summary

Submitter:	Velano Vascular, Inc. 4040 Locust St Philadelphia PA 19102	
Contact Person:	Tiffini Diage Consulting Director Regulatory Affairs Phone: 707.799.6732 E-mail: tdiage@raechelon.com	
Date Prepared:	10/2/15	
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: <ul style="list-style-type: none"> • K142946 – TIVA™ 	
Device Description:	<p>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.</p> <p>The device comes in two sizes compatible with 20 and 22 gauge PIV's, respectively.</p>	
Indication for Use:	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.	
	TIVA (Subject Device)	TIVA Blood Specimen Collection Device (Predicate Device)
510(k) Number	To be determined	K142946
Decision Date		
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	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.	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.
Intended Use	Same	Venous blood drawing
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
Blood Control Mechanism	Cap on female luer and clamp on flexible tubing	Cap on female luer
Materials		
Tubing	Same	Transparent Flexible
Performance Specifications		
Compatible PIV Sizes	Same	14G – 22G
Tubing Length	Same	6” and 12”
Inner Diameter (ID) of Tubing	Same	20G = 0.022” 22G = 0.018”
Sample collection	Same	Male luer connection to PIV, 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
Discussion of Differences	<p>The subject device has a clamp on the flexible tubing where the predicate device did not. This clamp has been added to serve as an additional blood control mechanism. This modification is being made based on user feedback that a clamp is preferred when using blood control devices with a syringe.</p> <p>Minor modifications have been made to the indication for use. The previously cleared indication for use included a technical requirement that TIVA be attached to the PIV “at time of IV catheter placement” because other blood control devices were attached at time of PIV placement and served as the blood control for the PIV. However newer PIVs and current clinical practice require a separate blood control valve or extension set be attached to all PIVs at time of placement. The TIVA device is detached after use and disposed of. The intended use of TIVA, a</p>	

blood collection device, is identical and unchanged from that of the originally cleared TIVA.

No changes were made to the intended use, materials, existing design specifications or performance specifications.

Performance testing provides objective evidence that the subject TIVA device does not introduce any new questions of safety or effectiveness compared to the predicate device and performs as intended.

Functional and Safety Testing:

To verify that the device design meets its functional and performance requirements, representative samples of the device underwent the following mechanical testing:

- Clamp functional testing
- Leak testing

No changes were made to patient contacting materials, sterilization method, and existing design specifications. The following testing was performed on the predicate device and are unchanged for the subject device:

- Joint strength testing
- Performance testing
- Leak testing
- Flow rate testing
- Biocompatibility testing per ISO 10993-1 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process, specifically:
 - Hemolysis and Intracutaneous Activity per ISO 10993-4
 - Cytotoxicity per ISO 10993-5
 - Sensitization per ISO 10993-10
 - Material Mediated Pyrogen and Systemic Toxicity per ISO 10993-11
- Sterilization validation testing per ISO-11137-1 Sterilization of Health Care Products. GAMMA Sterilization Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices (Overkill method)

Conclusion:

The TIVA device is substantially equivalent to the predicate device listed above. This conclusion is based upon the identical intended use, design specifications, patient contacting materials, manufacturing and sterilization processes. Additional bench testing (leak testing) demonstrates the modified TIVA device performs as intended and is substantially equivalent to the predicate TIVA.