K103260 p1/3

FEB 18 2011

5.0 Traditional 510(k) Summary

Submitter Information	
Name	VasoNova, Incorporated
Address	155 Jefferson Drive, Suite 100 Menlo Park, CA 94025
Phone number	(650) 388-5605
Fax number	(650) 388-5611
Establishment Registration Number	3006795936
Name of contact person	Kim Tompkins, RN, MBA
Date prepared	October 29, 2010
Name of device	
Trade or proprietary name	Vascular Positioning System™ (VPS™ System) Console
Common or usual name	Catheter, Ultrasound, Intravascular
Classification name	Diagnostic intravascular catheter, Class II
Classification panel	Cardiovascular
Regulation	21 CFR §870.1200
Product Code(s)	OBJ
Legally marketed device(s) to which equivalence is claimed	FlowPICC Console (K081626) Sapiens™ Tip Location System (TLS) (K093775)
Reason for 510(k) submission	Expanded labeling
Device description	The VPS System consists of a VPS Console and VPS Stylet. The VPS Console consists of two key integrated software-driven components: a data acquisition module; and a PC with processing and display capabilities. The data acquisition module of the console transmits and receives ultrasound data while receiving electrical signals from the heart through sensors mounted at the tip of the VPS Stylet. Using signals gathered by the data acquisition module, the graphical user interface of the PC provides the user with guidance for tip positioning. The VPS Stylet is a polyimide tube containing a Doppler sensor on a coax cable and an intravascular electrocardiogram (ivECG) signal sensing stainless steel wire. The Doppler sensor and the exposed portion of the ivECG are located at the distal end of the stylet and are used to detect and transmit physiological information to the VPS Console for analysis. The proximal end contains a connector to the VPS Console or to an extension cable that in turn connects to the VPS Console. The stylet can be inserted and removed from any catheter with a luminal diameter of at least 0.021 inches.

Intended use of the device	The intended use of the VPS Stylet and Console (VPS System) is to quickly and accurately guide market available peripherally inserted central catheters (PICCs) to the goal location which is the lower third of the SVC or at the cavo-atrial junction.
Indications for use	The VPS Stylet and Console are indicated for guidance and tip positioning for central venous catheters. The Console is intended for use with the stylet supplied by VasoNova. The VPS System consists of a Console and associated power supply and cabling and a stylet. The VPS Console, when used with the VPS Stylet, provides real-time catheter tip location information by using the patient's physiological (cardiac electrical activity and blood flow) information. When the VPS System guidance indicator shows a blue bull's-eye, the catheter tip is in the desired location. The VPS System is indicated for use as an alternative method to fluoroscopy or chest x-ray for central venous catheter tip placement confirmation in adult patients. Limiting but not contraindicated situations for this technique are in patients where alterations of cardiac rhythm change the presentation of the P-wave as in atrial fibrillation, atrial flutter, severe tachycardia and pacemaker-driven rhythm, and in central venous catheterization procedures performed through femoral or saphenous vein access which change the presentation of the P-wave. In such patients, who are easily identifiable prior to central venous catheter insertion, the use of an additional method is required to confirm catheter tip location.

SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE

Characteristic	VPS Console	FlowPICC Console (K081626)	Sapiens TLS (K093775)
Guidance indicator	Colored icons, waveform data	Colored icons, waveform data	Waveform data
Guidance signal type(s)	ivECG, Doppler ultrasound	ivECG, Doppler ultrasound	ivECG
Signal Conductor	Two conductor stylet wires	Two conductor stylet wires	Saline column via saline adapter or commercially-available (unspecified) conducting stylet or guidewire via electrical adapter
Acoustic Output	One setting; not controlled by the user	One setting; not controlled by the user	N/A
Method of Use	Percutaneous Intravascular	Percutaneous Intravascular	Percutaneous Intravascular
User Interface	PC-based system with keyboard and touch screen and mouse	PC-based system with keyboard and touch screen and mouse	PC-based system with keyboard and mouse
Software Interface	Custom GUI	Custom GUI	Custom GUI

PERFORMANCE DATA

SUMMARY OF NON-CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE

Performance Test Summary-New Device:

Characteristic	Standard/Test/FDA Guidance	Results Summary
Electromagnetic Compatibility	IEC 60601-2:2007	Compliant
Electrical Safety and Acoustic Safety	IEC 60601-1:1988 + A1:1991; A2:1995 IEC 60601-1-4:1996 + A1:1999 (Cons. Ed 1.1) IEC 60601-2-37:2001 +A1:2004; A2:2005 VasoNova SOP	Compliant

SUMMARY OF CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE AND/OR OF CLINICAL INFORMATION

Clinical Performance Data/Information.

The VPS System correctly indicated proper PICC tip placement in 98.4% of the placement procedures in a prospective, single-armed, open design clinical study of 77 patients.

CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA

The vast similarities of the VPS Console to the VasoNova FlowPICC Console predicate device support the substantial equivalence in intended use, function, and basic composition. The non-clinical testing to voluntary standards and applicable FDA guidance documents provide additional evidence the VPS Console is substantially equivalent to the VasoNova FlowPICC Console predicate device in terms of safety, efficacy, and performance.

The clinical testing of the VPS Console supports the substantial equivalence in indications for use to the Romedex Sapiens™ TLS predicate device.

The minor differences between the VPS Console and the predicate devices do not raise new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

VasoNova, Incorporated
c/o Ms. Kim Tompkins
VP, Regulatory/Clinical
Corporate Compliance Officer
155 Jefferson Drive, Suite 100
Menlo Park, CA 94025

FEB 18 2011

Re: K103260
Trade/Device Name: Vascular Positioning System™ (VPS™) Console
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic intravascular catheter
Regulatory Class: Class II (two)
Product Code: OBJ
Dated: February 1, 2011
Received: February 3, 2011

Dear Ms. Tompkins:

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.

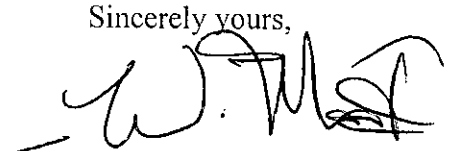
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K103260

4.0 Indications for Use Statement

510(k) Number: To be determined

Device Name: VasoNova™ Vascular Positioning System™ (VPS™ System) Console

Intended Use: The VPS Stylet and Console are indicated for guidance and tip positioning for central venous catheters. The Console is intended for use with the stylet supplied by VasoNova. The VPS System consists of a Console and associated power supply and cabling and a stylet. The VPS Console, when used with the VPS Stylet, provides real-time catheter tip location information by using the patient's physiological (cardiac electrical activity and blood flow) information. When the VPS System guidance indicator shows a blue bull's-eye, the catheter tip is in the desired location. The VPS System is indicated for use as an alternative method to fluoroscopy or chest x-ray for central venous catheter tip placement confirmation in adult patients.

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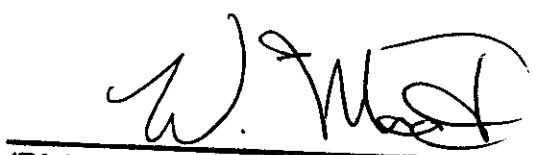
Prescription Use: **YES** AND/OR Over-the-Counter Use: **NO**

(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K103260