5.0 Traditional 510(k) Summary

FEB 18 2011

510(k) SUMMARY

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92

Submitter Information	
Name	VasoNova, Inc.
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 27, 2010
Name of device	
Trade or proprietary name	Vascular Positioning System™ (VPS™ System) Stylet
Common or usual name	Catheter, Ultrasound, Intravascular
Classification name	Class II
Classification panel	Cardiovascular
Regulation	21 CFR §870.1200
Product Code(s)	OBJ
Legally marketed device(s) to which equivalence is claimed	FlowPICC Stylet (K081625) 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 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. 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 VSP Stylet. Using signals gathered by the data acquisition module, the graphical user interface of the PC provides the user with guidance for tip positioning.
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 cavo-atrial junction near the sino-atrial node.
Indications for use	The VPS Stylet and Console are indicated for guidance and tip positioning for central venous catheters. The Stylet provides stiffness for use in placement of the catheter, intravascular capability for ECG detection and recording and intravascular ultrasound for catheter guiding and positioning. The VPS Stylet, when used with the VPS Console, 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 bullseye, 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	New Device	Predicate
Materials, design	6 foot long polymeric tube which contains a Doppler sensor at the distal tip and an intravascular electrocardiogram (ivECG) signal sensing wire.	Identical (FlowPICC, K081625)
Intended Use	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.	Sapiens™ TLS is indicated for use as an alternative method to chest X-ray or fluoroscopy for central venous catheter tip placement confirmation in adult patients. (Sapiens TLS, K093775)

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
Performance Testing:	Tensile strength, torque strength, tip flexibility, catheter compatibility and electrical safety testing were performed on the VPS Stylet	Met all specifications
Biocompatibility Testing	Cytotoxicity: ISO Elution Test (MEM extract), Cytotoxicity: ISO Direct Contact, Cytotoxicity: ISO Agar Diffusion Test, Murine Local Lymph Node Assay, Hemolysis, Partial Thromboplastin Test, Intracutaneous (intradermal) Reactivity Test (ISO), Acute systemic toxicity test, Ames Mutagenicity Test, Prothrombin Time Test, Thrombogenicity study in Dogs (ISO), ISO implant test (7 days), ISO implant test (90 days)	Compliant with ISO 10993-1:2003
Sterilization and Shelf-life Testing:	Sterilization validation and EtO Residuals testing per ANSI-AAMI-ISO 11135-1:1994 – Sterilization Validation. Shelf-life testing to 24 months has been performed.	Passed

Comparative Performance Information Summary			
Characteristic	Requirement	New Device	Predicate Device(s)
Sterility Biocompatibility ECG Ultrasound	Sterile	Sterile	Same Same Same Same (FlowPICC, only)

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 study clinical study of 77 patients.

CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA

The VPS Stylet is identical in design and materials to the FlowPICC Stylet (K081625) and has been clinically demonstrated to be substantially equivalent to the Sapiens™ TLS Tip Location System (K093775) with regard to intended use.

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: K103255
Trade/Device Name: Vascular Positioning System™ (VPS™) Stylet
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 2, 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

4.0 Indications for Use Statement

510(k) Number: To be determined

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

Intended Use: The VPS Stylet and Console are indicated for guidance and tip positioning for central venous catheters. The Stylet provides stiffness for use in placement of the catheter, intravascular capability for ECG detection and recording and intravascular ultrasound for catheter guiding and positioning. The VPS Stylet, when used with the VPS Console, 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 bullseye, 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.

Prescription Use: **YES** (Part 21 CFR 801 Subpart D) AND/OR Over-the-Counter Use: **NO** (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 K103255