510(k) SUMMARY

Submitter:	Vital Access Corporation
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Date 510(k) Summary Prepared:	September 6, 2013

SEP 13 2013

Proprietary Name:	VWING™
Common or Usual Name:	Vascular Needle Guide
Classification Name:	Subcutaneous, implanted intravascular infusion port and catheter
Classification Reference:	21 CFR § 876.5540
Proposed Regulatory Class:	Class II
Proposed Product Code:	

Predicate Devices:	K990803 - Medisystems Corp. Medisystems Buttonhole Needle Sets K926139 - BARD Access Systems, Inc. Cathlink 20 Titanium Port w/ Att. Polyurethane Cath

Device Description:
The VWING vascular needle guide has been designed to facilitate repeated needle access to the vasculature. The VWING vascular needle guide is an accessory for constant site or "buttonhole" method of needle insertion and is indicated for use for patient therapies requiring repeated access to the vascular system, such as hemodialysis. It is a single piece of titanium device that is implanted subcutaneously and attached to the outside of the vasculature, including on arteriovenous fistulae (AVF). The VWING acts as a guide for needles and accommodates currently available 15-17 gage needles to accurately cannulate the targeted vessel.

Intended Use / Indications for Use:
The VWING Vascular Needle Guide is indicated for use as an access device accessory on arteriovenous fistulas (AVF) for hemodialysis procedures using a constant site or "buttonhole" method of needle insertion.

Comparison of Technological Characteristics:

	VWING™	Bard Cathlink 20 Implanted Port	Medisystems Buttonhole Needle Sets
Materials	Titanium	Titanium	Stainless Steel
Design: Repeated Access	The device is designed to provide long-term repeated access to the vascular system.	The device is designed to provide long-term repeated access to the vascular system.	Single Access Event
Design: Implantable	The device is designed to be implanted subcutaneously and attached to the exterior surface of the target vessel.	The device is designed to be implanted subcutaneously and attached to the subcutaneous tissues surrounding a vessel, with its catheter dwelling inside the target vessel.	Not implantable
Design: Needle Guide	The access device has a semi-circular or round palpation ridge that leads into a conical funnel, aiding in finding the vessel location and guiding the needle into the single vessel cannulation site to allow access	Needle is guided into the port by the funnel shaped entrance and then into the needle channel.	Needle
Design: Vessel Entry	The device itself has no intravascular component. The device guides a sharp or buttonhole needle to the vessel wall where it may enter the vessel lumen. The device allows the needle to be held at a consistent angle during treatment by facilitating a single vessel access site at the device and a single skin insertion site as indicated	The device guides a needle-catheter to its funnel opening, after which the needle's catheter portion passes through an angled pathway and through a silicone septum, allowing access to the catheter which extends into the accessed vessel.	The needle directly enters a vessel by passing through the skin and subcutaneous tissue, then through the vessel wall into the vessel lumen.

	by the Instruction for Use.		
Design: Base	The vessel side of the access device is curved to match the curvature of the target vessel, creating a channel that helps to immobilize patient's vasculature for access during cannulation.	Consists of a titanium base. Elongated design with a round funnel shaped entrance.	N/A
Design: Suture Slots	The device has suture slots along its sides and at its front and back to help to secure the implant to the vessel wall.	The device has suture slots that are located along its sides to help secure the implant.	N/A
Design: Components	The device is a composed of a titanium funnel and titanium beads which are sintered to form a single piece titanium device.	The device is composed of a titanium port with a septum, connected to an indwelling catheter.	A hollow rigid needle cannula mounted in a hub bonded to a flexible tube and locking connector that allows attachment to other compatible devices. Different degrees of needle tip sharpness are offered. Sharp versions allow for the creation of the scar tunnel or buttonhole. Duller versions are used for repeated access of the created tunnel.
Chemical Composition	N/A	N/A	N/A
Energy Source	N/A	N/A	N/A

Summary of Performance Testing:
The VWING Vascular Needle Guide was verified and validated according to Vital Access procedures for product design and development. Bench testing was performed to demonstrate equivalence of the subject device to the predicate devices. Biocompatibility testing according to ISO 10993-1 was performed. Sterilization validations were performed in accordance with ISO 11137-2. Packaging validations and ship testing were performed in accordance with ISO 11607-1, ISO 11607-2, ASTM F1980-07, ASTM F2096-11, ASTM F88-09, and ASTM D4169-09 to ensure that sterility is maintained throughout the product's labeled shelf life. MR compatibility testing was performed pre FDA Guidance 'Establishing Safety and Compatibility of Passive Implants in the

Magnetic Resonance (MR) Environment' in accordance with ASTM F2052-06, ASTM F2213-06, ASTM F2119-07, and ASTM F2182-11.

Pre-clinical safety and efficacy testing was conducted by using an animal model. Three individual animal tests were conducted ranging in duration from 5 weeks to 6 months. Throughout these pre-clinical tests, the VWING was evaluated for its ability to safely facilitate access to a vessel for hemodialysis procedures.

A first in human clinical evaluation was conducted in New Zealand to demonstrate the feasibility and safety of the VWING as a method of providing dialysis access to patients with difficult to access fistulas using the buttonhole, or single site, cannulation technique.

The VWING was also evaluated in a prospective, multicenter IDE clinical study (SAVE Trial) to demonstrate safety and effectiveness of the device in providing access to previously uncannulatable segments of arteriovenous fistulae. At the three month primary endpoint follow-up, 96% of examined patients achieved access through a VWING. No new concerns of safety and effectiveness for a long-term vascular access device were observed during the trial. The occurrence rate of safety related events was within expectation and demonstrated the safety of the VWING Vascular Needle Guide. The rates of sepsis and study related serious adverse events were very low relative to standard fistula access: 0.04 and 0.31, respectively. All serious adverse events were resolved in the course of the study, leaving the fistula intact and functional. There were no study related deaths.

Conclusions:
The indications for use for the VWING Vascular Needle Guide is substantially equivalent to the indications for use for the predicate devices. Any differences in the technological characteristics between the devices do not raise any new issues of safety or efficacy. Thus, the VWING Vascular Needle Guide is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

September 13, 2013

Vital Access
% Christopher Phillips
Director of Quality Assurance and Regulatory Affairs
Vital Access Corporation
2302 South Presidents Drive, Suite C
Salt Lake City, UT 84120

Re: K130873
Trade/Device Name: VWING™ Vascular Needle Guide
Regulation Number: 21 CFR 876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: Class II
Product Code: PFH
Dated: August 3, 2013
Received: August 5, 2013

Dear Christopher Phillips,

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,

Herbert P. Lerner -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130873

Device Name: VWING™ Vascular Needle Guide

Indications for Use: The VWING Vascular Needle Guide is indicated for use as an access device accessory on arteriovenous fistulas (AVF) for hemodialysis procedures using a constant site or "buttonhole" method of needle insertion.

Prescription Use ___X___ (Part 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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S