JUL 17 2014

8. 510(k) Summary

In accordance with 21 CFR 807.87(h), a 510(k) Summary (21 CFR 807.92) follows:

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number: K140504

Applicant Information:

Date Prepared:	February 22, 2014
Name:	Vascular Pathways, Inc.
Address:	1847 Trade Center Way Naples, FL 34109
Phone:	239-254-0391

Contact Person: Scott Pease, VP of RA and QA

1847 Trade Center Way
Naples, Fl 34109
Cell – 678-689-8010
e-mail: spease@vascularpathways.com

Device Information:

Device Trade Name:	AccuCath BC Intravascular Catheter System
Common Name:	Intravascular Catheter
Classification Name(s):	Intravascular Catheter.
Product Code/ Regulation:	FOZ / 21 CFR 880.5200
Classification:	Class II

Predicate Devices:

Becton Dickinson BD INSYTE AUTOGUARD BC device (K110443),
Ethicon Endo-Surgery PROTECTIV* ACUVANCE IV Catheter System (K012128)
Vascular Pathways, Inc., Rapid Intravascular Catheter Start System (K112347)

Device Description:

The AccuCath BC Intravascular Catheter System has a usable length catheter of 2.25 inches in 18, 20 and 22 Gauge sizes. The devices are single use, sterile intravascular catheters designed to be inserted into a patient's vascular system to sample blood, monitor blood pressure, or administer fluids intravenously. This longer AccuCath BC catheter is identical to the AccuCath with the addition of needle echogenicity and a septum with plunger integrated into the catheter hub. The AccuCath BC catheter's hub has a built in blood control septum. The blood control feature is a single-use septum that automatically activates to stop the blood flow in the catheter hub when the needle is removed from the catheter during initial insertion by the clinician. Blood flow from the catheter hub will be restricted immediately after the needle retraction until a secure luer connection is made. The flow path is permanently opened once a secure luer connection has been made. Similar to the original AccuCath system, the device is provided with a safety mechanism which allows the needle to be shielded following placement of the catheter. All devices have the basic structure of a protective cover, a catheter with a bier lock fitting, an echogenic needle connected to a flashback chamber, a safety container, a guide wire within the lumen of the needle which is connected to a slider and a spring and release button.

Premarket Notification 510(k) Summary - Continued

Indications for Use:

The AccuCath BC Intravascular Catheter System is inserted into a patient's vascular system to sample blood, monitor blood pressure, or administer fluids intravenously. This device may be used with consideration given to adequacy of vascular anatomy, appropriateness of the solution being infused, and duration of therapy. The AccuCath BC is suitable for use with low pressure power injectors having a maximum pressure setting of 300 psi and maximum flow rate of 6mL/second.

Comparison to Predicate Devices:

The AccuCath BC Intravascular Catheter System has the same intended use, mechanism of action, and basic design attributes as the BD INSYTE AUTOGUARD BC device (K110443), the Ethicon PROTECTIV* ACUVANCE IV Catheter System (K012128) and the Vascular Pathways, Inc., Rapid Intravascular Catheter Start System (K112347) (the predicate devices). It has the same indications for use as the BD INSYTE AUTOGUARD BC device – adding power injection to the previously cleared Rapid Intravascular Catheter Start System indication consistent with the Ethicon PROTECTIV* ACUV ANCE IV Catheter System (K012128). Performance data demonstrates substantially equivalence in terms of safety and effectiveness to the predicate devices.

Performance Testing:

Biocompatibility and functional bench testing performed by Vascular Pathways, Inc. demonstrate the substantial equivalence, in terms of the safety and effectiveness, of the AccuCath BC Intravascular Catheter System to the predicate devices cited. In vitro bench testing included an assessment of all design input requirements and confirmation that the output of the design process met all design input requirements as follows:

1.	ISO 10993-1:2009, Biological Evaluation of Medical Devices- Part I: Evaluation and Testing
2.	ISO 10555-1: 1995 - Sterile, Single Use intravascular Catheters - Part 1: General Requirements
3.	ISO 10555-5: 2012 - Sterile, Single Use Intravascular Catheters - Part 5: Over-Needle Peripheral Catheters
4.	ISO 594 -1:1986 Conical Fittings with a 6% (Luer) Taper for Syringes, Needles and Certain Other Equipment - Part 1: General Requirements
5.	ISO 594-2:1998 Conical Fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 2: Lock Fittings
6.	ASTM F640:2012 — Std Test Methods for Determining Radiopacity for Medical Use
7.	ISO 11607-1:2006 — Packaging for terminally sterilized medical devices — Part 1: Requirements for materials...
8.	ISO 11607-2:2006 — Packaging for terminally sterilized medical devices — Part 2: Validation requirements..
9.	ASTM D4169-09, Std Practice for Performance Testing of Shipping Containers and Systems.
10.	ASTM F2096-11, Standard Test Method for Detecting Gross Leaks in Medical Packaging by Internal Pressurization (Bubble Test).
11.	ASTM F88/F88M-09, Standard Test Method for Seal Strength of Flexible Barrier Materials.
12.	ASTM F1980-07 (2011) Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.
13.	Guidance Document No. 934 - Medical Devices with sharps injury prevention features (August 9, 2005)
14.	AAMI TIR16:2000 – Process Development and Performance Qualification for Ethylene Oxide Sterilization – Microbiological aspects

Summary:

Based upon the device description and test data provided in this submission the AccuCath BC Intravascular Catheter System is substantially equivalent to the predicate devices cited.

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

July 17, 2014

Vascular Pathways, Inc.
Mr. Scott Pease
Vice President of Regulatory Affairs and Quality Assurance
1847 Trade Center Way
Naples, FL 34109

Re: K140504
Trade/Device Name: AccuCath BC Intravascular Catheter System
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: FOZ
Dated: June 10, 2014, 2014
Received: June 16, 2014, 2014

Dear Mr. Pease:

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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140504

Device Name

AccuCath BC Intravascular Catheter System

Indications for Use *(Describe)*

The AccuCath BC Intravascular Catheter System is inserted into a patient's vascular system to sample blood, monitor blood pressure, or administer fluids intravenously. This device may be used with consideration given to adequacy of vascular anatomy, appropriateness of the solution being infused, and duration of therapy. The AccuCath BC is suitable for use with low pressure power injectors having a maximum pressure setting of 300 psi and maximum flow rate of 6mL/ second.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Digitally signed by Richard C. Chapman -S
Date: 2014.07.16 16:29:43 -04'00'

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