SECTION 13. 510(K) SUMMARY

SEP 2 2 2011

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: _____

Applicant Information:

Date Prepared:	July 15, 2011
Name:	Vascular Pathways, Inc.
Address:	1847 Trade Center Way Naples, FL 34109
Phone:	(239) 254-0391
Fax:	(239) 513-1533
Contact Person:	Michael A Daniel / Steven J Hoffman
Phone Number:	(415) 407-0223
Office:	(925) 254-5228
Facsimile Number:	(925) 254-5187

Device Information:

Classification:	Class II
Trade Name:	Rapid Intravascular Catheter Start System
Common Name:	Intravascular Catheter
Classification Name:	Intravascular Catheter
Product Code/ Regulation:	FOZ / 21CFR 880.5200

Predicate Device:

The RIVS 18, 20 and 22 gauge devices are substantially equivalent in intended use and method of operation to the following predicate device:

K073241 – Vascular Pathways, Inc., Rapid Intravascular Catheter Start System

Device Description:

The RIVS 18, 20 and 22 Gauge devices are single use, sterile intravascular catheters designed to provide access to veins. The devices are 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 luer lock fitting, a 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.

Indications for Use:

The Vascular Pathways RIVS system is indicated for use to sample blood, monitor blood pressure, or administer fluids intravenously. This device may be used with consideration given to patient size, appropriateness of the solution being infused, and duration of therapy.

Comparison to Predicate Device:

The design of the three RIVS devices is essentially the same device as the predicate RIVS with moderate design modifications to reduce cost of goods and improve manufacturability. The products share common features such as identical operating principles, basic design, performance characteristics, anatomical site for venous access, safety, and physical characteristics.

The devices are packaged sterile and are for single patient use. Further, the modified RIVS, two new gauge devices and the predicate device have the same intended use, which is to provide access to veins. Verification and validation testing provided proof the modifications met the design specifications and user needs and biocompatibility testing provided evidence there were no changes to that safety aspect of the device.

Summary:

Based upon the intended use, product technical information, performance testing and biocompatibility information provided in this pre-market notification, the modified RIVS 22 gauge and the additional 18 and 20 gauge devices have been shown to be substantially equivalent to the currently cleared predicate RIVS device in terms of design, performance and intended use. There are no new issues raised regarding safety or effectiveness of the modified or additional gauge devices.

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

Vascular Pathways, Incorporated
C/O Michael A. Daniel
President
Daniel & Daniel Consulting
8 Snowberry Court
Orinda, California 94563

SEP 22 2011

Re: K112347
Trade/Device Name: Vascular Pathways RIVS Rapid Intravascular Catheter Start System
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: FOZ
Dated: September 8, 2011
Received: September 14, 2011

Dear Mr. Daniel:

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 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,

Anthony D. Watson

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

8.3 INDICATIONS FOR USE

510(k) Number (if known): K112347

Device Name: Vascular Pathways RIVS Rapid Intravascular Catheter Start System

Indications For Use:

The Vascular Pathways RIVS system is indicated for use to sample blood, monitor blood pressure, or administer fluids intravenously. This device may be used with consideration given to patient size, appropriateness of the solution being infused, and duration of therapy.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 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 Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K112347