K073241

Appendix A: 510 (K) Summary of Safety and Effectiveness for the Rapid Intravascular Catheter Start System

A.	Submitter:	Vascular Pathways, Inc. 713 Sandoval Way Hayward, Ca 94544
B.	Contact:	Mary Pascual Gallup VP of Regulatory Affairs Vascular Pathways Phone: 510-487-1561 X17 Fax : 510-487-1569
C.	Trade name	RIVS - Rapid Intravascular Catheter Start system
D.	Common Name/ Product Code/Class	Intravascular Catheter 80 FOZ Class II
E.	Regulation Number	21 CFR 880.5200
F.	Device Description	The device is a single use, sterile intravascular catheter designed to provide access to veins. The device is provided with a mechanism which allows the needle to be shielded following placement of the catheter.
G.	Statement of Intended Use	The Vascular Pathways RIVS is intended 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.
H.	Performance Standards	The RIVS device does or will conform to the following recognized standards: ISO 10555-1: 1995 Sterile, Single Use Intravascular Catheters, ISO 594-1: 1986 Conical Fittings with 6% (luer) – Part 1, ISO 7864: 1993 Sterile Hypodermic needles for single use, and AAMI TIR 33 – Sterilization of healthcare products – Substantiation of 25Kgy as a sterilization dose – VD max
I.	Substantial Equivalence Conclusion	The Vascular Pathways - intravascular catheter is substantially equivalent to the Angiocath® Autoguard ™ and Insyte® Autoguard™ Catheter cleared by the FDA under K984059. The RIVS share the same intended use; operation, access to anatomical sites, safety and physical characteristics, and therefore is substantially equivalent to the Angiocath® Autoguard ™ and Insyte® Autoguard™ Catheter. There are no new issues raised regarding safety or effectiveness of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 8 2008

Ms. Mary Pascual Gallup
Vice President of Regulatory Affairs
Vascular Pathways, Incorporated
713 Sandoval Way
Hayward, California 94544

Re: K073241
Trade/Device Name: Vascular Pathways RIVS Rapid Intravascular Catheter Stat System
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: FOZ
Dated: November 14, 2007
Received: November 16, 2007

Dear Ms. Gallup:

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.

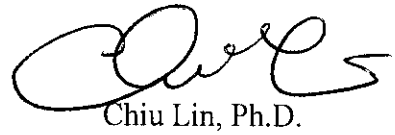
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
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Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Appendix B: Indications for Use

510(K) Number: K073241

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.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use:___X____ or Over the Counter_____
(Per 21 CFR 801.109

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K073241