K990823

JUL 23 1999

Precision Vascular Systems, Inc.

Summary of Safety and Effectiveness Information

PVS 1400 Guidewire

Regulatory Authority: Safe Medical Devices Act of 1990, 21 CFR 807.92

1. Device Name:

Trade Name: **PVS 1400 Guidewire**

Common Name: **Guidewire**

Classification Name: **Catheter guide wire**

2. Establishment Name and Registration Number:

Name: **Precision Vascular Systems, Inc.**

Number: **To be applied for**

3. Classification:

WIRE, GUIDE, CATHETER 74DQX II 870.1330

§ 870.1330 Catheter guide wire. (a) Identification. A catheter guide wire is a coiled wire that is designed to fit inside a percutaneous catheter for the purpose of directing the catheter through a blood vessel. (b) Classification. Class II (performance standards).

Device Class: Class II
Classification Panel: Cardiovascular
Product Code: 74DQX

4. Special Controls:

Not applicable to this device.

5. Labeling:

IMPORTANT: Please see attached labeling.

Federal (United States) law restricts this device to sale, distribution and use by or on the order of a physician only.

Warnings and cautions:	Please see Appendix I.
Known contraindications to date:	Please see Appendix I.
Side-effects and possible complications:	Please see Appendix I.
Pre-operatively:	Please see Appendix I.
Intra-operatively:	Please see Appendix I.
Post-operatively:	Please see Appendix I.

6. Equivalent/Predicate Devices:

ACS Hi-Torque Floppy II® (K881897), Microvena UltraSelect® Nitinol Guidewire (K910280) Standard and Floppy Tip, Boston Scientific/Medi-Tech Target Stubbie® (K873543), and Cordis Corp. Wizdom® (K953760).

7. Device Description:

These guidewires are intended for use in percutaneous procedures to introduce and position catheters and other interventional devices within the coronary and peripheral vasculature.

The PVS 1400 Guidewire is a 0.014" outside diameter, single-use guidewire, which is used to gain intravascular access to and to facilitate the positioning and exchange of catheters in small diameter, tortuous vasculature for coronary and peripheral diagnostic or interventional procedures. The wire can be torqued to facilitate navigation through the vasculature. Refer also to the description in Appendix VI.

Materials: The proximal wire material is stainless steel. The guidewire is coated to provide lubricity. The tip material of the guidewire is nitinol. Refer also to the material description in Appendix II.

Instrumentation: There is no instrumentation applicable to this device.

Voluntary Standards: US Food and Drug Administration-mandated performance standards for this device do not exist. This device and its method of manufacture comply with applicable harmonized standards, including EN 46001/ISO 9001/Medical Device Directive 93/42/EEC Appendix II, and the Quality System Regulation (21 CFR Part 820).

Performance Data: The PVS 1400 Guidewire performance was compared to predicate devices by testing tip flexibility, tensile strength, torqueability, torsional stiffness and torsional strength, catheter compatibility, and coating flake resistance. Please refer to Appendix III for results of the testing performed on the PVS 1400 Guidewire.

Tip Flexibility - The PVS 1400 Guidewire had similar values of tip flexibility compared to three predicate devices, similar to two predicates but less flexible than one.

Tensile Strength - The PVS 1400 Guidewire had similar values of tensile strength compared to two predicate devices, similar to one predicate device and lower tensile strength than the other.

Torqueability - The PVS 1400 Guidewire had much better torqueability (i.e., much less difference between proximal input angle and distal tip output angle in a simulated tortuous anatomy) than the predicate device against which it was compared.

Torsional Stiffness and Strength - The PVS 1400 Guidewire had approximately 7.5 times higher torsional stiffness than the ACS predicate device against which it was compared. The PVS 1400 Guidewire had approximately 3 times higher torsional strength than the ACS predicate device against which it was compared. The PVS 1400 Guidewire had higher torsional stiffness than the Microvena UltraSelect® Standard Tip and the Boston Scientific/Medi-Tech Target Stubbie® predicate devices, it had higher torsional strength than these two predicate devices, and it had approximately the same or more turns to failure as these two predicate devices.

Catheter Compatibility - The PVS 1400 Guidewire had catheter compatibility that was similar to that of the three predicate devices against which it was compared.

Coating Flake Resistance - The PVS 1400 Guidewire had coating adhesion/flake resistance that was similar to that of the predicate device against which it was compared.

The results of the testing establish that the PVS 1400 Guidewire is substantially equivalent in physical performance characteristics to its predicate devices.

Biocompatibility Data: The PVS 1400 Guidewire biocompatibility was tested per FDA guidance for an external communicating device in contact with circulating blood for less than 24 hours. Tests performed include cytotoxicity, systemic toxicity, intracutaneous reactivity (irritation), sensitization, and hemocompatibility (hemolysis and thrombogenicity). Please refer to Appendix III for results of the testing performed on the PVS 1400 Guidewire.

The results of the testing establish that the PVS 1400 Guidewire is biocompatible.

Storage and Handling: Store in a cool, dark, dry place. Handle with care.

Packaging: The expiration date for sterilization must be checked on the package label prior to use. Only those products which are to be used prior to the shelf-life expiration date may be considered sterile. The instructions for opening the package are written on the individual unit's packaging. Every precaution must be taken to ensure sterility when opening the device's packaging and when inserting

it. Once the package is opened or damaged outside the sterile field, it can no longer be considered sterile. Inspect all packaging upon receipt for evidence of damage. Damaged packaging renders the product unsafe for use. Return all devices whose packaging appears damaged upon receipt. Subsequently damaged product packaging requires product replacement. Product for use in the operating room must be opened, handled and placed into use following accepted operating room sterile technique.

Sterilization: The guidewires are supplied pre-sterilized by Gamma radiation; alternatively, the devices may be pre-sterilized with ethylene oxide (EtO). The selected radiation dose is 20 K Grey minimum. The Sterility Assurance Level (SAL) of the guidewire is at least 10^{-6}. The device may not be secondarily cleaned or resterilized. Validation of the recommended sterilization cycle is achieved through the overkill method. In addition, testing will be performed by an independent contract laboratory to demonstrate that the product sterilized in the validated EtO cycle does not contain residuals above the levels specified:

Ethylene Oxide	≤ 25 ppm
Ethylene Chlorohydrin	≤ 25 ppm
Ethylene Glycol	≤ 250 ppm

8. Applicant's Name and Address:

Precision Vascular Systems, Inc.
360 Wakara Way
Salt Lake City, Utah 84108
801.585.3430 phone
801.581.1151 fax

9. Company Contact:

Kent Backman
Precision Vascular Systems, Inc.
360 Wakara Way
Salt Lake City, Utah 84108
801.585.3430 phone
801.581.1151 fax

10. Submission Correspondent:

James P. Stout
200 Gregory Lane, Suite C-100
Pleasant Hill, California 94523
925.356.2640 phone
925.356.2654 fax

11. Manufacturing Facility:

The device will be manufactured either at the company's facility or at a qualified contract manufacturer; in either event the devices will be manufactured under a quality system compliant with the Quality System Regulation (21 CFR Part 820) and with EC regulations for medical device manufacture (EN 46001/ISO 9001/Medical Device Directive 93/42/EEC Appendix II), prior to the first shipment of devices in commercial distribution.

12. Modified Device Data:

This section is not applicable to this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 23 1999

Mr. John R. Ragazzo
Precision Vascular Systems
360 Wakara Way
Salt Lake City, UT 84108

Re: K990823
PVS 1400 Guidewire
Regulatory Class: II (two)
Product Code: 74 DQX
Dated: June 25, 1999
Received: June 29, 1999

Dear Mr. Ragazzo:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Precision Vascular Systems, Inc.

PVS 1400 Guidewire

Indications for Use

510(k) Number (if known): K990823

Device Name: ***PVS 1400 Guidewire***

Indications for Use:

1. These guidewires are intended for use in percutaneous procedures to introduce and position catheters and other interventional devices within the coronary and peripheral vasculature
2.
3.
4.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

CONFIDENTIAL/ PROPRIETARY

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices

510(k) Number _____