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K053268

Summary of Safety and Effectiveness

Prepared November 22, 2005
Revised March 2, 2006

General Provisions

Submitter of 510(k) Premarket Notification:	Boston Scientific - Precision Vascular 2405 West Orton Circle West Valley City, UT 84119 Phone: 801.974.1700 Fax: 801.974.1740
Contact Person:	Rick Gaykowski VP, Regulatory/Clinical Affairs Quality Systems & Operations
Device Trade Name:	PV 2000 ***Synchro*®2** Guidewire
Device Generic Name:	Guidewire

Predicate Devices

The predicate devices are listed in the table below.

Device	Manufacturer	510(k) Number/Date	Pro Code
***Synchro*™** .014"	Precision Vascular	K032146, 12 August 2003	DQX
***Synchro*™** .010"	Precision Vascular	K032146, 12 August 2003	DQX
***Synchro*™** .016"	Precision Vascular	K050964, 13 June 2005	DQX
Transend	Target Therapeutics	K971254, 01 July 1997*	DQX

* This information is assumed based upon our best knowledge.

Classification

Class II, 21 CFR 870.1330, Wire, Guide, Catheter 74DQX

Performance Standards

Performance standards have not been established by FDA under section 514 of the Federal Food, Drug and Cosmetic Act.

Intended Use

The PV 2000 ***Synchro*®2** Guidewire series of products is intended for peripheral and neurovascular use. The device can be used to selectively introduce and position catheters and other interventional devices within the peripheral and neurovasculature. This device should be used only by physicians trained in percutaneous, intravascular techniques and procedures.

Device Description

The PV 2000 is a member of the ***Synchro*®** Guidewire family of products having a 0.014" outside diameter, being a sterile, single use/disposable product, with a shapeable tip which is used to gain intravascular access to and facilitate the positioning and exchange of interventional devices in small diameter, tortuous vasculature for peripheral and neuro diagnostic and interventional procedures. The guidewire can be torqued to facilitate navigation through the vasculature. A torque device, (Merit Medical (K936032)) is supplied with the wire to facilitate deployment & positioning. A guidewire

introducer/shaping mandrel (B. Braun (K760389)) is also supplied and may be used to aid introduction of the guidewire into the catheter hub and/or hemostasis valve and to gently shape the guidewire's distal flexible tip, if desired, according to standard practice. Neither the guidewire introducer nor the torque device are intended to enter the body. The product is projected to be provided in a 100cm – 300cm length range, with 200cm being nominal. The Nitinol tip length is projected to be presented in a 35cm length. A traditional range of flexibility profiles shall also be provided, ranging from support (stiff) to flex (soft). The device is coated on the outer diameter with a lubricious coating over the distal portion of the device. The marker coil is platinum wire at the distal tip of the device to aid visualization under fluoroscopy. The subject device has the ability to access distal, tortuous vasculature, with steerability and torque transmission properties.

Technological Characteristics

Technological similarities between the subject PV 2000 ***Synchro®2*** Guidewire and the PVS 1300 ***Synchro***™ predicate remain identical. This is also true for competitive predicate device features including the basal design and dimensions, generic materials & construction, and hydrophilic coating. There are no new questions raised regarding safety or efficacy of the PVS 1300 ***Synchro®*** 0.014" Guidewire.

Safety and Performance Tests

Biocompatibility of the PV 2000 ***Synchro®2*** Guidewire materials have been verified in accordance with ISO 10993-1, Biological Evaluation of Medical Devices - Part 1. Materials test results confirmed biocompatibility of the subject device when tested as an external communicating, blood contact, short duration (<24 hours) device.

Performance testing of materials comprising the PV 2000 ***Synchro®2*** Guidewire was conducted in accordance with ISO 11070:1998, Sterile, Single-Use Intravascular Catheter Introducers. Verification testing for the subject device included dimensional inspection, fatigue assessment, tip flexibility, tip shaping, tensile strength, guidewire compatibility testing and performance under simulated conditions. Subject product testing has yielded acceptable safety & performance outcomes.

In addition, torsional strength, torqueability, and EO sterilization adoption tests also yielded acceptable results. The results of these tests, in conjunction with the substantial equivalence claims as outlined in the premarket notification, effectively demonstrate the PV 2000 ***Synchro®2*** Guidewires' substantial equivalence to the cited predicate devices.

Summary of Substantial Equivalence

Based on the indications for use, technological characteristics, and safety and performance testing, the subject PV 2000 ***Synchro®2*** Guidewire meets the minimum requirements that are considered adequate for its intended use and is substantially equivalent in design, materials, sterilization, principles of operation and indications for use to current commercially available guidewires/cited predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 13 2006

Boston Scientific – Precision Vascular
c/o Mr. Rick Gaykowski
V.P. Regulatory/Clinical Affairs
Quality Systems and Operations
2405 West Orton Circle
West Valley City, UT 84119

Re: K053268
PVS 2000 ***Synchro***®2 Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Wire, Guide, Catheter
Regulatory Class: Class II
Product Code: DQX
Dated: February 15, 2006
Received: February 16, 2006

Dear Mr. Gaykowski:

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) 276-0120. 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,

B Zuckerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K053268

Device Name: PV 2000 ***Synchro*®2** Guidewire

Indications For Use: The PV 2000 ***Synchro*®2** Guidewire series of products are intended for general intravascular use, including the neuro and peripheral vasculature. The device can be used to selectively introduce and position catheters and other interventional devices within the peripheral and neurovasculature. This device should be used only by physicians trained in percutaneous, intravascular techniques and procedures.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K053268