K033742

JAN 1 2 2004

Section 4 Summary of Safety and Effectiveness

(Pursuant To Section 12 per 21 CFR 807.92 of the SAFE MEDICAL DEVICES ACT of 1990)

General Provisions

1. Submitter's Name and Address	Boston Scientific Corporation One Scimed Place Maple Grove, Minnesota 55311
2. Contact Person	Deborah Thomas Regulatory Affairs Specialist 763-494-2078 (phone) 763-494-2981 (fax) thomasd@bsci.com
3. Date Prepared	November 26, 2003
4. Proprietary Name	Boston Scientific Corporation V-18 Control Wire
5. Common or Usual Name	Catheter Guide Wire
6. Product Code	74DQX
7. Classification of Device	Class II, 21 CFR Part 870.1330

Predicate Devices

Boston Scientific Strike™ (V-18) Control Guide Wire
(K934359; cleared October 7, 1993)

Device Description

The 110 cm V-18 Control Wire wire is for use in the percutaneous introduction of catheters including Hemodialysis Access Management procedures. The 110 cm V-18 Control Guide Wire is a sterile, single-use wire that is available in a 110cm nominal wire length, a nominal of 0.018" diameter, a nominal 8 cm taper length, and a shapeable tip

Section 4 Summary of Safety and Effectiveness

The 110 cm V-18 Control Wire is identical to Boston Scientific's currently marketed V-18 Strike Control Wire with the exception of the length and indication. The length of the 110 cmV-18 Control Wire is 110cm, while the lengths of the V-18 Strike Control Wire includes 150cm, 200cm, and 300cm offerings. With the exception of the length, the guide wire design is identical to the V-18 Strike Control Wire (**K934359, cleared October 7, 1993**). The V-18 Strike Control Wire guide wire is for use in the percutaneous introduction of catheters. The 110cm V-18 Control Wire includes this indication and also includes hemodialysis AV access management interventions.

The core is a tapered stainless steel wire which provides the pushability, flexibility, torquability and steerability needed to maneuver into tortuous vessels. The most distal portion of the wire is shapeable. The distal end of the core is covered with a heat-flow polyurethane compounded with tungsten. The tungsten provides the radiopacity needed for visualization. The heat-flow is coated with a hydrophillic polymer for ease of use and enhances appearance.

A torque device, also cleared in the V-18 Strike 510(k) (K934359) is included in the package and is intended for use at the proximal end of the guide wire to allow manipulation of the wire during the percutaneous procedure.

Intended Use

The 110cm V-18 Control Wire is intended for general intravascular use including the placement of PTA balloon catheters requiring an 0.018" guide wire in hemodialysis AV access procedures. The wire can be torqued to facilitate placement of diagnostic or therapeutic catheters. This device is intended for peripheral vascular use only. A torque device is included with each wire to facilitate directional manipulation of the guide wire.

Section 4 Summary of Safety and Effectiveness

Technological Characteristics

The 110 cm V-18 Control Guide Wire will incorporate equivalent packaging, fundamental technology, manufacturing, and sterilization as those featured in the predicate Boston Scientific legally marketed guide wire, the V-18 Strike Control Guide Wire. The 110 cm V-18 Control Wire will incorporate an equivalent design as the V-18 Strike Control Guide Wire, except for the 110cm length. The currently marketed V-18 Strike Control Wire is offered in 150cm, 200cm, and 300cm lengths. The 110 cm V-18 Control Wire design is identical to the V-18 Strike Control Wire except for the length.

Non-Clinical Test Summary

Device compatibility testing and biocompatibility testing were performed to support a determination of substantial equivalence. The results of these tests met minimum requirements and are adequate for it's intended use. No new safety or performance issues were raised during the testing regimen.

Since the 110cm V-18 guide wire design is identical to the currently marketed V-18 Strike Control Wire, except for the length, all data that was submitted for the V-18 Strike Control Wire is applicable to the 110cm V-18 Guide Wire. The following previous test data for V-18 Strike Control Wire was not repeated, but is representative of the 110cm V-18 Control Wire, since the distal wire segments are identical. These tests include: Distal Tip Torsion, Combined Load Failure, Torque Response, Tip Flexibility, Polyurethane/PTFE Coating Adherence Test, Torque Slip Force, Pull Tensile Test, Collett Release Test, and Deformation Test.

Conclusion

Based on the Indications for Use, technological characteristics, and results of the invitro testing and evaluation, the 110cm V-18 Control Wire has been shown to be adequate for its intended use and is considered to be substantially equiva-lent to the V-18 Strike Guide Wire (K934359; cleared October 7, 1993).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 2 2004

Boston Scientific Corporation
c/o Ms. Deborah Thomas
Regulatory Affairs Specialist
One Scimed Place
Maple Grove, MN 55311

Re: K033742
Trade/Device Name: Boston Scientific V-18 Control Wire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: November 26, 2003
Received: November 28, 2003

Dear Ms. Thomas:

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 (301) 594-__. 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/dsma/dsmamain.html

Sincerely yours,

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): K033742

Device Name: V-18 Control Guide Wire

Indications For Use:

The 110cm V-18 Control Wire is intended for general intravascular use including the placement of PTA balloon catheters requiring an 0.018" guide wire in hemodialysis AV access procedures. The wire can be torqued to facilitate placement of diagnostic or therapeutic catheters. This device is intended for peripheral vascular use only. A torque device is included with each wire to facilitate directional manipulation of the guide wire.

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 Cardiovascular Devices

510(K) Number K033742 (SM. K)