MAR 1 9 2002

K014195

Summary of Safety and Effectiveness

Section 6

Submitter's Information

Name and Address
Boston Scientific Scimed, Inc.
One Scimed Place
Maple Grove, Minnesota 55311

Contact Person
Mark Murphy
763-494-2377

Date
December 20, 2001

Device Name

Proprietary Name
Boston Scientific Corporation Kayak™ Hydrophilic Guide Wires

Common or Usual Name
Kayak™ Guide Wires

Classification Name
Catheter Guide Wire

Predicate Devices:

The following predicate devices are currently marketed.

Product	510(k)	Clearance Date
Terumo Radifocus Glidewire	K961445	07/09/1996
Cordis Hydronol Steerable Guidewire	K973845	01/05/1998

Summary of Safety and Effectiveness, Continued — Section 6

Models Available

The Kayak™ Hydrophilic Guide Wires are steerable guide wires available in a nominal diameter of 0.035 and 0.038 inches and nominal lengths of 80, 150 and 180 centimeters. The available tip flexibilities will be

- Standard,
- Stiff
- Long Taper.

The distal three centimeters of all models are available in straight and pre-formed angled tip design.

Device Components

The Kayak™ Hydrophilic Guide Wire consists of the following three components:

- nickel titanium core
- polyurethane jacket
- hydrophilic coating

Polyurethane Jacket

The full length of the guide wire has a polyurethane jacket containing tungsten encasing the core wire.

Hydrophilic Coating

The full length of the guide wire has a hydrophilic coating for lubricity.

Summary of Safety and Effectiveness, Continued — Section 6

Intended Use

The Boston Scientific Corporation (BSC) Kayak™ Hydrophilic Guide Wires are intended to facilitate the placement of a catheter during diagnostic or interventional procedures. The wire can be torqued to facilitate navigation through tortuous arteries and/or avoid unwanted side branches. This device is not intended for use in the coronary arteries or the neurovasculature.

Summary of Technological Characteristics

The Kayak™ Hydrophilic Guide Wires are manufactured in a similar manner to legally marketed BSC hydrophilic guide wires and microcatheters, including the Renegade Braided Microcather (K973645) and the predicate device – Terumo Radifocus Glidewire (K961445).

Non-Clinical Test Summary

Testing and evaluation of the guide wires included:

- tensile strength
- torque strength
- cantilever stiffness
- tip prolapse
- peel test
- lubricity and durability
- biocompatibility
- product shelf life

Results

Test results demonstrate that the Kayak™ Hydrophilic Guide Wires met all evaluation acceptance criteria and are adequate for their intended use.

Summary

The Kayak™ Hydrophilic Guide Wires are considered to be substantially equivalent to guide wires currently marketed by BSC and for Terumo Corporation based on a comparison of intended use, design and the results of *in vitro* testing and evaluation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 9 2002

Mr. Mark Murphy
Regulatory Affairs Specialist
Boston Scientific Scimed, Inc.
One Scimed Place
Maple Grove MN 55311

Re: K014195
Trade/Device Name: Kayak™ Hydrophilic Guide Wires
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter guide wire.
Regulatory Class: Class II
Product Code: DOX
Dated: December 20, 2001
Received: December 21, 2001

Dear Mr. Murphy:

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 and additionally 21 CFR Part 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

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

Enclosure

Indications for Use

Section 2

510(k) Number K014195

Device Name: Kayak™ Hydrophilic Guide Wires

Indications for Use: The Boston Scientific Corporation (BSC) Kayak™ Hydrophilic Guide Wires are intended to facilitate the placement of a catheter during diagnostic or interventional procedures. The wire can be torqued to facilitate navigation through tortuous arteries and/or avoid unwanted side branches. This device is not intended for use in the coronary arteries or the neurovasculature.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over The Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K014195