

MAR 19 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.

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

## Summary of Safety and Effectiveness, Continued

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**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.

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**Device Components**

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

- nickel titanium core
  - polyurethane jacket
  - hydrophilic coating
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**Polyurethane Jacket**

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

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**Hydrophilic Coating**

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

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**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.

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**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 Microcatheter (K973645) and the predicate device – Terumo Radifocus Glidewire (K961445).

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**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.

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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

**MAR 19 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

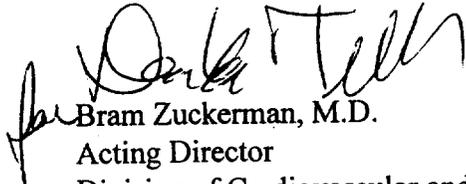
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forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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,

A handwritten signature in black ink, appearing to read "Bram Zuckerman".

Bram Zuckerman, M.D.

Acting Director  
Division of Cardiovascular and  
Respiratory Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

