JAN 2 2 2002

K020028

Section 6 Summary of Safety and Effectiveness

(Pursuant To Section 12 of the SAFE MEDICAL DEVICES ACT of 1990)

6.1 General Provisions

Submitter's Name and Address	Boston Scientific Scimed, Inc. One Scimed Place Maple Grove, Minnesota 55311
Contact Person	Todd Kornmann (763) 494-2467
Classification Name	Similar to Diagnostic Intravascular Catheters (21CFR Part 970.1200)
Common or Usual Name	Coronary or Peripheral Guide Catheter
Proprietary Name	Boston Scientific 5F, 7F, and 8F Mach1 Guide Catheters

6.2 Name of Predicate Device

Boston Scientific Scimed
6F Mach1 Guide Catheter

6.3 Device Description

The Boston Scientific 5F, 7F, and 8F Mach1 catheters are similar to the currently marketed 6F Mach1 Guide Catheter, with the addition of three French sizes to the catheter line.

The Boston Scientific Mach1 catheters are designed to provide a pathway through which medical instruments, such as balloon dilatation catheters, guide wires or other diagnostic or therapeutic devices, may be introduced. These devices are not intended for use in the cerebral vasculature. The Mach1 catheters will be offered in 5F, 6F, 7F, and 8F sizes and are available in lengths ranging from 40-125 cm, with optional side holes. The devices are provided sterile and intended for one procedure use only.

The Mach1 catheters are manufactured using similar construction techniques as other currently marketed Boston Scientific guide catheters. The catheter shaft consists of three layers: the inner, middle and outer layers. The outer layer is composed of four segments,(5F has three segments) inclusive of the proximal shaft segment, but not including the distal tip. The outer layer segments are composed of the same material,

(Arnitel) but use varying durometers of the Arnitel (polyether-ester) shaft materials providing specific flexibility zones over the length of the catheter. The tip consists of a reinforced tip portion and a non-reinforced tip portion. The 6F, 7F and 8F tip is made of Hytrel, while the 5F has an Arnitel tip.

6.4 Intended Use

The Mach1 Guide Catheters are intended for use in general intravascular and coronary applications designed to provide a pathway through which medical instruments, such as balloon dilatation catheters, guide wires or other therapeutic devices may be introduced. These devices are not intended for use in the cerebral vasculature.

6.5 Summary of Technological Characteristics

Same as currently marketed 6F Mach1 guide catheters, cleared for market under K010874, June 21, 2001.

6.6 Non-clinical Test Summary

Functional testing consisted of shaft and distal segment tensile and elongation, tip tensile, tip deflection, hub to shaft tensile, pressure shaft burst and leak, torque response, lumen integrity and radiopacity. Biocompatibility, package pouch burst, and product shelf life testing have also been conducted. Test results verified that the 5F, 7F and 8F Mach1 catheters are adequate for the intended use. The 5F, 7F and 8F Mach1 guide catheters are considered substantially equivalent to the currently marketed 6F Mach1 guide catheter based on a comparison of the intended use, the device 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

JAN 2 2 2002

Mr. Todd Kornmann
Sr. Regulatory Affairs Specialist
Boston Scientific Scimed, Inc.
One Scimed Place
Maple Grove MN 55311

Re: K020028
Trade/Device Name: 5F, 7F and 8F Mach1 Guide Catheters
Regulation Number: 21 CFR 870.1250
Regulation Name: Catheter, Percutaneous
Regulatory Class: Class II
Product Code: DQY
Dated: January 3, 2002
Received: January 4, 2002

Dear Mr. Kornmann:

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

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,

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

Enclosure

Section 4 — Indications for Use

510(k) Number (if known) K020028

Device Name: 5F, 7F, and 8F Mach1 Guide Catheters

Indications for Use:

Mach1 Guide Catheters are intended for use in general intravascular and coronary applications. They provide a pathway through which medical instruments, such as balloon dilatation catheters, guide wires or other therapeutic devices may be introduced. These devices are not intended for use in the cerebral vasculature.

(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 K020028