Section 4 Summary of Safety and Effectiveness

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

General Provisions

Submitter's Name and Address	Boston Scientific, Scimed, Inc. One Scimed Place Maple Grove, Minnesota 55311
Contact Person	Candice Burns (763) 494-2845
Classification Name	Percutaneous Transluminal Angioplasty Balloon Dilatation Catheter (21CFR Part 870.1250)
Common or Usual Name	Balloon Dilatation Catheter
Proprietary Name	Boston Scientific Ultra-soft™ SV Balloon Dilatation Catheter

Classification

According to Section 13 of the Federal Food, Drug and Cosmetic Act, the device classification is Class II, Performance Standards

Predicate Devices

Boston Scientific Gazelle™ Balloon Dilatation Catheter
(K001134; cleared April 7, 2000)

Device Description

The Ultra-soft SV Percutaneous Transluminal Angioplasty (PTA) catheter is a Monorail™ catheter with a balloon near the distal tip. The balloon is designed to provide an inflatable segment of known diameter and length at recommended pressures. The distal segment of the balloon catheter is dual lumen and coaxial. The outer lumen is used for inflation of the balloon. The wire lumen permits the use of guidewires (≤0.018 in / 0,46 mm) to facilitate advancement of the catheter to and through the stenosis to be dilated. The Ultra-soft SV will be available in the following sizes.

Section 4 Summary of Safety and Effectiveness

Device Description (continued)

	Balloon Diameter						
Length Balloon/Catheter	**4.0mm**	**4.5mm**	**5.0mm**	**5.5mm**	**6.0mm**	**6.5mm**	**7.0mm**
15 mm/90 cm	X	X	X	X	X	X	X
15 mm/150 cm	X	X	X	X	X	X	X
20 mm/90 cm	X	X	X	X	X	X	X
20 mm/ 150 cm	X	X	X	X	X	X	X

Intended Use

The proposed Ultra-soft SV Balloon Dilatation Catheter is indicated for percutaneous transluminal angioplasty (PTA) of the iliac, femoral, ilio-femoral, popliteal and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

Technological Characteristics

The Ultra-soft SV catheter will incorporate a substantially equivalent design, packaging, fundamental technology, manufacturing, sterilization and intended use as those featured in predicate Boston Scientific legally marketed balloon catheters.

Safety and Performance

Bench testing and biocompatibility testing were performed to support a determination of substantial equivalence. The results of these tests provide reasonable assurance that the proposed device has been designed and tested to assure conformance to the requirements for its intended use. No new safety or performance issues were raised during the testing regimen.

Conclusion

Based on the Indications for Use, technological characteristics, and safety and performance testing, the Ultra-soft SV Balloon Dilatation Catheter has been shown to be adequate for its intended use and is considered to be substantially equivalent to the Gazelle PTA Catheter (K001134; cleared April 7, 2000).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 0 8 2002

Ms. Candice Burns
Boston Scientific Scimed, Inc.
One Scimed Place
Maple Grove, MN 55311-1566

Re: K021735
Ultra-soft™ SV Balloon Dilatation Catheter
Regulation Number: CFR: 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY, LIT
Dated: May 24, 2002
Received: May 28, 2002

Dear Ms. Burns:

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.

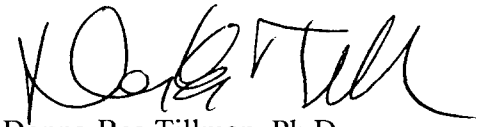
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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) 594-4586. 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,



Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 2 — Indications for Use

510(k) Number (if known) K021735

Device Name: Ultra-soft™ SV Balloon Dilatation Catheter

Indications for Use:

The Ultra-soft SV Balloon Dilatation Catheters are recommended for percutaneous transluminal angioplasty of the iliac, femoral, ilio-femoral, popliteal, renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K021735

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

(Optional Format 1-2-96)