K020012

JAN 2 9 2002

Summary of Safety and Effectiveness

General Provisions	**Trade Name**: Renegade™ Fiber Braided Microcatheter **Classification Name:** Diagnostic Intravascular Catheter
Name of Predicate Devices	Renegade™ Fiber Braided Microcatheter
Classification	Class II
Performance Standards	Performance Standards have not been established by FDA under Section 514 of the Food, Drug and Cosmetic Act
Intended Use and Device Description	The Renegade™ Fiber Braided Microcatheters are intended for general intravascular use, including neuro, peripheral and coronary vasculature. The catheter can be coaxially tracked over a steerable guidewire in order to access distal, tortuous vasculature. Once the subselective region has been accessed, the catheter can be used for controlled and selective infusion of diagnostic, embolic, or therapeutic materials into vessels.
Biocompatibility	The Renegade™ Fiber Braided Microcatheters have been tested for biocompatibility per ISO 10993. All data demonstrate this device is biocompatible for its intended use.
Summary of Substantial Equivalence	The Renegade™ Fiber Braided Microcatheters have been tested and compared to the predicate device. All data gathered demonstrate this device as substantially equivalent. No new issues of safety or efficacy have been raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 9 2002

Ms. Jodi Lynn Greenizen
Regulatory Affairs Project Manager
Boston Scientific Scimed, Inc.
One Scimed Place
Maple Grove MN 55311

Re: K020012
Trade/Device Name: Renegade™ Fiber Braided Microcatheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic intravascular catheter.
Regulatory Class: Class II
Product Code: DQO
Dated: December 31, 2001
Received: January 3, 2002

Dear Ms. Greenizen:

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,

for 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

510(k) Number (if known)	Unknown K020012
Device Name:	Renegade™ Fiber Braided Microcatheter
Indications for Use	The Renegade™ Fiber Braided Microcatheters are intended for general intravascular use, including neuro, peripheral and coronary vasculature. The catheter can be coaxially tracked over a steerable guidewire in order to access distal, tortuous vasculature. Once the subselective region has been accessed, the catheter can be used for controlled and selective infusion of diagnostic, embolic, or therapeutic materials into vessels.

(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 K020012

Prescription Use ✓ OR Over-The Counter Use_____
(Per 21 CFR 801.109) (Optional Format 1-2-96)