K993648

Section III - 510(k) Summary

NOV 24 1999

General Information

Submitter	Boston Scientific Corporation Northwest Technology Center, Inc. 17425 N.E. Union Hill Road Redmond, WA 98052
Contact Person	Cyndy Adams 425-556-1570 (phone) 425-558-1400 (fax)
Classification Name	Catheter, Peripheral, Atherectomy (per 21 CFR 870.4875)
Common or Usual Name	Rotational Angioplasty System Rotablator® Rotational Angioplasty System with the RotaLink® Exchangeable Catheter
Classification Panel	Cardiovascular

Name of Predicate Device

Predicate Device Peripheral Rotablator® Rotational Angioplasty System with the RotaLink® Exchangeable Catheter	510(k) Reference No. K970296

Device Description

The Rotablator® Rotational Angioplasty system uses a high speed, rotating, diamond-coated burr to ablate occlusive material and restore luminal patency. The burr spins at 140,000-190,000 RPM and ablates material into very fine particles that are carried distally and removed via the reticuloendothelial system. The Rotablator System with Exchangeable Catheter comprises four main components: advancer, catheter with diamond-coated burr, console and foot pedal, and guide wire.

Intended Use

The peripheral Rotablator system is intended for percutaneous use in peripheral vessels in patients with occlusive atherosclerotic disease who are acceptable candidates for bypass graft surgery or percutaneous transluminal angioplasty.

Summary of Technological Characteristics

The proposed Rotablator system is similar in construction and materials to the currently marketed Rotablator system.

Test Summary

The proposed Rotablator system is considered to be substantially equivalent to the previously marketed Rotablator system based on a comparison of the intended uses and designs and results of the testing and evaluations performed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 24 1999

Ms. Cyndy Adams
Sr. Regulatory Affairs Specialist
Boston Scientific Corporation
17425 N.E. Union Hill Road
Redmond, WA 98052-3376

Re: K993648
Trade Name: Peripheral Rotablator® Rotational Angioplasty System With the RotaLink™ Exchangeable Catheter
Regulatory Class: II
Product Code: MCW
Dated: October 28, 1999
Received: October 29, 1999

Dear Ms. Adams:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to

your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

Celia M. Witten, Ph.D., M.D.
Acting Director
Division of Cardiovascular,
Respiratory and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section I - Indications for Use

510(k) Number (if known)

Device Name	Peripheral Rotablator® Rotational Angioplasty System with the RotaLink™ Exchangeable Catheter
Indications for Use	The peripheral Rotablator system is intended for percutaneous use in peripheral vessels in patients with occlusive atherosclerotic disease who are acceptable candidates for bypass graft surgery or percutaneous transluminal angioplasty.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K993648