K992142

JUL 2 1 1999

Special 510(k) : Device Modification
SCIMED Angiographic Catheters
Hub Material Change

Section 4 Summary of Safety and Effectiveness

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

I. General Provisions

Submitter's Name and Address	Boston Scientific SCIMED, Inc. One SCIMED Place Maple Grove, Minnesota 55311
Contact Person	Melanie Raska (612) 494-2962
Classification Name	Diagnostic Intravascular Catheters (21CFR Part 870.1200)
Common or Usual Name	Diagnostic Intravascular Catheter
Proprietary Name	SCIMED® EXPO and Impulse Angiographic Catheters
Name of Predicate Devices	SCIMED® EXPO and Impulse Angiographic Catheters

II. Device Description

The modified SCIMED EXPO and Impulse angiographic catheters are the same as the SCIMED EXPO and Impulse angiographic catheters currently on the market with the exception of the new hub material.

III. Intended Use

SCIMED EXPO and Impulse angiographic catheters are designed to provide a pathway to be used for delivering contrast media to selected sites in the vascular system during an angiographic procedure.

IV. Summary of Technological Characteristics

Same as currently marketed EXPO and Impulse angiographic catheters.

V. Non-clinical Test Summary

Functional testing was conducted to verify the integrity of the modified hub. Biocompatibility testing was conducted on the new hub material.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 21 1999

Ms. Melanie Raska
Regulatory Affairs Specialist
Boston Scientific SCIMED, Inc.
One Scimed Place
Maple Grove, MN 55311-1566

Re: K992142
Trade Name: SCIMED EXPO and Impulse Angiographic Catheters
Regulatory Class: II
Product Code: DQO
Dated: June 23, 1999
Received: June 24, 1999

Dear Ms. Raska:

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,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 3 — Indications for Use

510(k) Number (if known) _____

Device Name: SCIMED® EXPO and Impulse Angiographic Catheters

Indications for Use:

The SCIMED EXPO and Impulse Angiographic Catheters are designed to provide a pathway to be used for delivering contrast media to selected sites in the vascular system during an angiographic procedure.

(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)

(Division Sign-Off) for TSC
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K992142

(Optional Format 1-2-96)