

510(k) Notification  
SCIMED Impulse Angiographic Catheters  
3 Year Shelf Life

**Section 3**

**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® Impulse Catheters

**II. Name of Predicate Devices** SCIMED® Impulse Catheters

**III. Device Description**

The Impulse angiographic catheters and packaging materials are the same as the Impulse catheters currently on the market. The packaging materials for all SCIMED Angiographic catheters have recently been tested to support a 3 year shelf life.

**IV. Intended Use**

SCIMED Impulse 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.

**V. Summary of Technological Characteristics**

Same as currently marketed Impulse catheters.

**VI. Non-clinical Test Summary**

Standard packaging testing was conducted to support a 3 year package shelf life.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

AUG 23 1999

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

Re: K992123  
Trade Name: SCIMED Impulse angiographic Catheters  
Regulatory Class: II (two)  
Product Code: 74 DQO  
Dated: June 22, 1999  
Received: June 23, 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 (Pre-market 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 pre-market 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.

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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) 594-4648. 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" (21 CFR 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, Ph.D.  
Director  
Division of Cardiovascular,  
Respiratory, and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Notification  
SCIMED Impulse Angiographic Catheters  
3 Year Shelf Life

Indications for Use

510(k) Number (if known) \_\_\_\_\_

Device Name: SCIMED® Impulse Angiographic Catheters

Indications for Use:

The SCIMED 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.

*Judith Danielescu for Chris Sloan 8/22/96*  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Cardiovascular, Respiratory,  
and Neurological Devices  
510(k) Number K992123

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

\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use  \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over The Counter Use \_\_\_\_\_

(Optional Format 1-2-96)