AUG 1 8 1998

K981788

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	SCIMED Life Systems, Inc. One SCIMED Place Maple Grove, Minnesota 55311
Contact Person	Melanie Raska (612) 494-2962
Classification Name	Similar to Diagnostic Intravascular Catheters (21CFR Part 870.1200)
Common or Usual Name	Coronary Guide Catheter
Proprietary Name	SCIMED® 6 French Wiseguide™ Guide Catheter

II. Name of Predicate Devices

SCIMED® 7 French Wiseguide™ and 6 French Cyber Guide Catheters, and Cordis® Corporation 6 French Vista Brite Tip™ Guide Catheters.

III. Device Description

The shaft of the 6 F Wiseguide guide catheter utilizes biocompatible materials and consists of the following three layers: 1) the inner layer that provides a low coefficient of friction and facilitates passage of medical devices such as stents, balloon dilatation catheters, guide wires or other therapeutic devices, 2) the middle layer that extends from the shaft to the tip to provide kink resistance and torque control; and 3) the outer layer which provides stiffness, backup support, curve retention and radiopacity.

In addition, the outer primary catheter shaft is constructed of various material durometers providing transitional flexibility to the distal curve area of the catheter.

The catheter is radiopaque to allow visualization under fluoroscopy during a procedure.

The devices will be provided sterile and are intended for one procedure use only.

Section 4 Summary of Safety and Effectiveness (cont.)

IV. Intended Use

The 6 F Wiseguide catheter is designed to provide a pathway through which medical instruments, such as stents, balloon dilatation catheters, guide wires or other therapeutic devices may be introduced. This device is not intended for use in the cerebral vasculature.

V. Summary of Technological Characteristics:

The 6 F Wiseguide catheter is similar to SCIMED's currently marketed 7 F Wiseguide catheter (K974684).

VI. Non-clinical Test Summary

Functional testing consisted of pressure burst, tip bond tensile, shaft tensile, hub tensile, material adhesion, tip coefficient of friction, force transmitted by catheter tip, torque response and dye flow. Test results verified that the 6 F Wiseguide catheter is adequate for its intended use. The 6 F Wiseguide catheter is considered substantially equivalent to guide catheters currently marketed by SCIMED and Cordis based on a comparison of intended use, the design, and the results of *in-vitro* testing and evaluation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 18 1998

Ms. Melanie Raska
Regulatory Affairs Specialist
Scimed Life Systems, Inc.
One Scimed Place
Maple Grove, MN 55311-1566

Re: K981788
Trade Name: Scimed 6 French Wiseguide Guide Catheter
Regulatory Class: II
Product Code: DQO
Dated: May 19, 1998
Received: May 20, 1998

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) 594-4618. 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, Respirator and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

AUG 1 8 1998

Section 2 — Indications for Use

510(k) Number (if known) _____

Device Name: SCIMED® 6 French Wiseguide™ Guide Catheter

Indications for Use:

SCIMED 6 French Wiseguide guide catheter is intended for use in general intravascular and coronary applications. It provides a pathway through which medical instruments, such as stents, balloon dilatation catheters, guide wires or other therapeutic devices may be introduced. This device is not intended for use in the cerebral vasculature.

(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)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K981788

(Optional Format 1-2-96)