JUN - 3 1997

K970823

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	Angela Raun (612) 494-2456
Classification Name	Similar to Diagnostic Intravascular Catheters (21CFR Part 870.1200)
Common or Usual Name	Coronary Guide Catheter
Proprietary Name	SCIMED® 8 French Wiseguide™ Guide Catheter

II. Name of Predicate Devices

SCIMED® 8 French Cyber™ Guide Catheters and Cordis® Corporation, 8 French Vista Brite Tip™ Guide Catheters

III. Device Description

The shaft of the 8 F Wiseguide guide catheter utilizes common biocompatible materials and consists of the following three layers: 1) the inner polytetrafluoroethylene (PTFE) layer that provides a low coefficient of friction and facilitates easy passage of medical devices such as balloon dilatation catheters, guide wires or other therapeutic devices, 2) the middle layer which is made of braided stainless steel wire that extends from the shaft to the tip to provide kink resistance, torque control and support and 3) the outer layer, manufactured from Pebax® and a radiopaque filler, which provides stiffness, memory and radiopacity.

In addition, the distal 5.8 to 17.5 inches (depending on the curve style) of the outer primary catheter shaft is constructed of multiple sections of Pebax. These sections are composed of durometers of Pebax providing a distal curve area of the catheter with transitional flexibility. The catheter is assembled as components over a core mandrel. The catheter shaft is then heat fused, forming a composite catheter shaft. This process results in a continuous inner and middle layer and a seamless outer shaft layer.

Section 4 Summary of Safety and Effectiveness, cont.

The distal tip is made of Pebax and is radiopaque to allow visualization under fluoroscopy during a procedure.

The catheters utilize a one piece Pebax hub/strain relief that is molded to the proximal end of the guide catheter shaft. The 8 F Wiseguide Guide Catheters have a 0.086" ID. The catheters will be available in lengths ranging from 40 to 125 cm, with optional side holes. The devices will be provided sterile and are intended for one procedure use only.

IV. Intended Use

The SCIMED guide catheters are designed to provide a pathway through which medical instruments, such as balloon dilatation catheters, guide wires or other therapeutic devices may be introduced. These devices are not intended for use in the cerebral vasculature.

V. Summary of Technological Characteristics:

The 8 F Wiseguide Guide Catheters are similar to SCIMED's currently marketed 8 F Cyber Guide Catheters with the exception of the distal flexible sections providing varying degrees of flexibility in the distal curve area.

VI. Non-clinical Test Summary

Functional testing consisted of pressure burst, tip bond tensile, shaft tensile, hub tensile, tip coefficient of friction, force transmitted by the catheter tip, and torque testing. Biocompatibility and shelf life testing has also been conducted. Test results verified that the 8 F Wiseguide catheter is adequate for its intended use. The 8 F Wiseguide guide catheters are 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

JUN 3 1997

Ms. Angela Raun
Sr. Regulatory Affairs Specialist
Scimed Life Systems, Inc.
One Scimed Place
Maple Grove, Minnesota 55311-1566

Re: K970823
SCIMED® 8 French Wiseguide™ Guide Catheter
Regulatory Class: II (two)
Product Code: DQY
Dated: March 5, 1997
Received: March 6, 1997

Dear Ms. Raun:

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 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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) 594-4648. 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 at (301) 443-6597.

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 2 — Indications for Use

510(k) Number (if known) K970823

Device Name: SCIMED® 8 French Wiseguide™ Guide Catheter

Indications for Use:

SCIMED guide catheters are intended for use in general intravascular and coronary applications. They provide a pathway through which medical instruments, such as balloon dilatation catheters, guide wires or other therapeutic devices may be introduced. These devices are 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,
Neurological Devices
510(k) Number K970823

(Optional Format 1-2-96)