APR 29 1998

K980360

Summary of Safety and Effectiveness — Section 4

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

General Provisions	Submitter's Name and Address	SCIMED Life Systems, Inc. One SCIMED Place Maple Grove, MN 55311
	Contact Person	Jill Townsend (612) 494-2359
	Classification Name	Catheter Guide Wire
	Common or Usual Name	PTCA Guide Wire
	Proprietary Name	SCIMED® Quest™ Floppy and Moderate Support Guide Wires
Name of Predicate Devices	Predicate Device	510(k) Reference No.
	ChoICE Guide Wire Family	K943192, K945129, K950113, K950141, K961015, K964551, K965023, K970244
	Luge Guide Wire	K973945
	Sceptor and Sceptor Exchange	K942333, K946240, K950534, K960563

Summary of Safety and Effectiveness, continued — Section 4

Device Description	The SCIMED Quest Floppy and Moderate Support Guide Wires are steerable guide wires available in a nominal diameter of 0.014 inches and nominal lengths of 182 and 300 centimeters. The available tip flexibilities will be Floppy and Moderate Support. The distal two centimeters of both models are radiopaque and available in either a straight shapeable or a pre-formed J-Tip.
Intended Use	The SCIMED Quest Floppy and Moderate Support Guide Wires are intended to facilitate the placement and exchange of balloon dilatation catheters or other therapeutic devices during PTCA or other intravascular interventional procedures. The Quest Floppy and Moderate Support Guide Wires are not intended for use in the cerebral vasculature. The devices are provided sterile and intended for one procedure only.
Summary of Technological Characteristics	The SCIMED Quest Floppy and Moderate Support Guide Wires utilize the same materials and methods of construction as the currently marketed SCIMED Guide Wires (ChoICE, Luge and Sceptor Families of Guide Wires).
Non-Clinical Test Summary	Testing and evaluation of the guide wires included tip tensile strength, tip torsion strength, combined load strength, tip flexibility, tip prolapse, J-tip curve retention, torque response, proximal spring coil joint shear strength, PTCA catheter compatibility/wire movement and lubricious coating adherence. Shelf Life testing is currently being conducted and will be submitted when it is completed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 29 1998

Ms. Jill Townsend
Regulatory Affairs Associate
SCIMED Life Systems, Incorporated
One SCIMED Place
Maple Grove. MN 55311-1566

Re: K980360
Trade Name: SCIMED® Quest™ and Zig Zag Guide Wires
Regulatory Class: II
Product Code: DQX
Dated: March 17, 1998
Received: March 18, 1998

Dear Ms. Townsend:

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. 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

Indications for Use

Section 2

510(k) Number

Device Name SCIMED® Quest™ Guide Wires

Indications for Use The SCIMED Quest Guide Wires are intended to facilitate the placement of balloon dilatation catheters or other therapeutic devices during PTCA or other intravascular interventional procedures. The SCIMED Quest Guide Wires 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)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
Neurological Devices
510(K) Number K980360