K964551

SCIMED®
Boston Scientific Corporation

SCIMED Life Systems, Inc.
One SCIMED Place
Maple Grove, MN 55311-1566
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MAY 21 1997

Summary of Safety and Effectiveness

Section 6

Submitter's Information

Name and Address
SCIMED Life Systems, Inc.
One SCIMED Place
Maple Grove, Minnesota 55311

Contact Person
Connie J. Del Toro
(612) 494-2656

Date
November 12, 1996

Device Name

Proprietary Name
SCIMED ChoICE Super Support PTCA Guide Wire
SCIMED ChoICE Plus Super Support PTCA Guide Wire
SCIMED ChoICE Exchange Super Support PTCA Guide Wire
SCIMED ChoICE Super Support II PTCA Guide Wire
SCIMED ChoICE Plus Super Support II PTCA Guide Wire
SCIMED ChoICE Exchange Super Support II PTCA Guide Wire

Common or Usual Name
PTCA Guide Wire

Classification Name
Catheter Guide Wire (per 21CFR 870.1330)

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Summary of Safety and Effectiveness, continued — Section 6

Predicate Devices

The ChoICE Super Support and Super Support II Guide Wire models are substantially equivalent to the following SCIMED products.

Product	510(k)	Clearance Date
ChoICE	K943192 K950141 K961015	November 22, 1994 March 3, 1995 May 15, 1996
ChoICE Plus	K945129 K961015	March 3, 1995 May 15, 1996
ChoICE Exchange	K950113 K961015	March 31, 1995 May 15, 1996
ChoICE PT Vision	K962572	Currently under review.

Device Description

The ChoICE Super Support and Super Support II Guide Wire models are steerable guide wires available in a nominal diameter of 0.014" and two tip configurations, straight shapeable and pre-formed J-Tip.

A polymer sleeve extending from the spring coil to the proximal fluorinated polymer coated core wire, surrounds the tapered core wire and is coated with ICE Hydrophilic Coating.

The available lengths for the Super Support and Super Support II Guide Wire will be:

- ChoICE -190 cm,
- ChoICE Plus-182 cm, and
- ChoICE Exchange-300 centimeters.

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Summary of Safety and Effectiveness, continued — Section 6

Intended Use

The ChoICE Super Support and Super Support II Guide Wire models are intended to facilitate the placement and exchange of balloon dilatation catheters or other therapeutic devices during PTCA or other intravascular interventional procedures. The ChoICE Guide Wire family is not intended for use in the cerebral vasculature. The devices are provided sterile and intended for one procedure only.

Summary of Technological Characteristics

The ChoICE Super Support and Super Support II Guide Wire models utilize the same materials and methods of construction as the currently marketed ChoICE Guide Wire family and the recently submitted ChoICE PT Vision Guide Wire family. The differences necessary to create the Super Support and Super Support II Guide Wire models are the slight variation of the distal core wire tapers and the reduced length of the polyurethane sleeve.

Non-Clinical Test Summary

Testing and evaluation of the guide wires included:

- Tip Tensile,
- Tip Torsion,
- Combined Load,
- Tip Flexibility,
- J-Tip Curve Retention,
- Torque Response, and
- Proximal Spring Coil Joint Shear Strength.

Results

Test results verified that the ChoICE Super Support and Super Support II Guide Wire models met all of the minimum requirements and are adequate for their intended use.

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Summary of Safety and Effectiveness, continued — Section 6

Non-Clinical Test Summary, continued

Summary

The Super Support and Super Support II models are considered to be substantially equivalent to the currently marketed ChoICE, ChoICE Plus, and ChoICE Exchange PTCA Guide Wires and the recently submitted ChoICE PT Vision Guide Wire family, based on a comparison of intended use, 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

MAY 21 1997

Ms. Connie J. Del Toro
Regulatory Affairs Associate
Scimed Life Systems, Inc.
One Scimed Place
Maple Grove, Minnesota 55311-1566

Re: K964551
SCIMED® ChoICE™ PTCA Guide Wires
SCIMED® ChoICE™ Plus PTCA Guide Wires
SCIMED® ChoICE™ Exchange PTCA Guide Wires
Super Support and Super Support II Models
Regulatory Class: II (two)
Product Code: DQX
Dated: March 3, 1997
Received: March 4, 1997

Dear Ms. Del Toro:

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

Indications for Use

Section 2

510(k) Number K96455 |

Device Name ChoICE PTCA Guide Wires
ChoICE Plus PTCA Guide Wires
ChoICE Exchange PTCA Guide Wires

Indications for Use

The SCIMED ChoICE Guide Wires are intended to facilitate the placement of balloon dilatation catheters or other therapeutic devices during PTCA or other intravascular interventional procedures. The ChoICE Guide Wire family 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, [redacted]
and Neurological Devices
510(k) Number K96455 |

(Optional Format 1-2-96)