

NOV 12 1998

**Summary of Safety and Effectiveness**

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**General Information**

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Submitter's Name and Address	SCIMED Life Systems, Inc. One SCIMED Place Maple Grove, MN 55311
Contact Person	Jill Munsinger (612) 494-2359
Classification Name(s)	Catheter Guide Wire, 21 CFR Part 870.1330; Transducer, Blood Pressure, Extra Vascular, 21 CFR Part 870.2850; Patient Transducer and Electrode Cable, 21 CFR Part 870.2900
Common or Usual Name(s)	PTCA Guide Wire Disposable Pressure Transducer Cable, Patient Transducer
Proprietary Name(s)	SCIMED® Informer™ Pressure Wire System
Product Code(s)	74 DQX (Catheter Guide Wire) 74 DRS (Transducer, Blood Pressure, Extra Vascular) 74 DRA (Patient Transducer and Electrode Cable)

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**Predicate Devices**

The SCIMED® Informer™ Pressure Wire is substantially equivalent to the products listed on the following page.

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## Summary of Safety and Effectiveness, continued

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**Intended Use** The SCIMED INFORMER™ Pressure Wire System is intended to monitor the mean intravascular blood pressure and to facilitate the placement of balloon dilatation catheters or other therapeutic devices during PTCA or other intravascular interventional procedures. The phasic wave signal of the INFORMER Pressure Wire System is intended to facilitate placement of the wire. The INFORMER Pressure Wire System is not intended for use in the cerebral vasculature.

The SCIMED INFORMER Pressure Wire System is not intended to be used in combination with any H.F. surgical equipment.

The SCIMED INFORMER Pressure Wire System is indicated for use with all physiological monitors that meet IEC 601-1, IEC 601-2-34 standards. These monitors are required to meet electrical isolation for Type CF applied parts.

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**Summary of Technological Characteristics**

The Informer™ System is substantially equivalent to the currently marketed SCIMED ChoICE™ and Sceptor PTCA Families of Guide Wires, the Namic Perceptor™ DT Disposable Transducer, the MEDEX TranStar Pressure Transducer, the BAXTER Edwards Permanent Cable Model PX-1800 and the Cardiometrics WaveWire/WaveMap Pressure System.

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**Non-Clinical Test Summary**

In-Vitro testing and evaluations were performed on the Informer™ Guide Wire, the Informer™ Disposable Transducer with Attached Cable, the Informer™ Permanent Cable and the complete Informer™ System. Standard guide wire tests were used to evaluate the Informer™ Guide Wire. The Informer™ Disposable Transducer experienced standard ANSI/AAMI BP-22 testing while the cable testing included Cable Connection Cycling, Disposable Transducer Cable Connector Tensile, Transducer Housing/Cable Tensile, Strain Relief and Permanent Cable Connector Tensile. System Response and Shelf Life testing was conducted on complete Informer™ System units.

Additionally, In-Vivo testing was conducted to compare pressure reading capabilities and guide wire performance characteristics to currently marketed devices.

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## Summary of Safety and Effectiveness, continued

Predicate  
 Devices,  
 continued

Product	510(k)	Clearance Date
ChoICE Guide Wire	K943192	November 22, 1994
	K945129	March 3, 1995
	K950141	March 3, 1995
	K950113	March 31, 1995
	K961015	May 15, 1996
	K965063	March 4, 1997
	K964551	May 21, 1997
Sceptor Guide Wire	K942333	August 31, 1994
	K946240	March 31, 1995
	K950534	April 28, 1995
	K960563	April 29, 1996
Namic Perceptor DT Disposable Transducer	K910764	April 22, 1991
Medex TranStar Pressure Transducer	K942377	August 16, 1994
Baxter Edwards Reusable PX-1800	K925638	October 18, 1993
Cardiometrics WaveWire/WaveMap Pressure System	K965140	August 18, 1997

Device  
 Description

The SCIMED® Informer™ Pressure Wire System consists of the following components:

- a guide wire,
- a disposable transducer with attached cable, and
- a permanent cable.

The guide wire is a steerable coronary guide wire available in a nominal diameter of 0.014 inches, overall lengths of 185 and 300 centimeters, radiopaque tip lengths of 3 and 5 centimeters, straight and J-tip configurations and one tip flexibility that falls between the ChoICE Floppy and Intermediate models, similar to the ChoICE Extra Support. The guide wire is designed to monitor intravascular pressures and to facilitate the placement of balloon dilatation catheters.

The disposable transducer with attached cable converts hemodynamic pressure signals from the guide wire into electrical signals. This transducer interfaces with standard physiologic monitors to display the electrical signals in phasic waveforms via the permanent cable.



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Jill Munsinger  
Regulatory Affairs Associate  
SCIMED Life Systems, Inc.  
One Scimed Place  
Maple Grove, MN 55311-1566

Re: K974241

Trade Name: SCIMED® Informer™ Pressure Wire System  
Regulatory Class: II  
Product Code: DQX  
Dated: August 13, 1998  
Received: August 14, 1998

Dear Ms. Munsinger:

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.

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) 594-4586. 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, Ph.D.  
Director  
Division of Cardiovascular, Respiratory  
And Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use Form

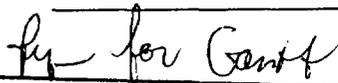
510(k) Number K974241

Device Name SCIMED® Informer™ Pressure Wire System

**Indications for Use** The SCIMED Informer™ Pressure Wire System is intended to monitor the mean intravascular blood pressure and to facilitate the placement of balloon dilatation catheters or other therapeutic devices during PTCA or other intravascular interventional procedures. The phasic wave signal of the INFORMER Pressure Wire System is intended to facilitate placement of the wire. The INFORMER Pressure Wire is not intended for use in the cerebral vasculature.

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\_\_\_\_\_  
(Division Chief)  
Division of \_\_\_\_\_  
and \_\_\_\_\_  
510(k) Number K974241

(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 \_\_\_\_\_