

K962572



SCIMED Life Systems, Inc.
One SCIMED Place
Maple Grove, MN 55311-1566
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DEC 17 1996

SECTION THREE-- SUMMARY OF SAFETY AND EFFECTIVENESS

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS
(Pursuant To Section 12 of the SAFE MEDICAL DEVICES ACT of 1990)
Prepared June 28, 1996

I. General Provisions:

Submitter's Name and Address: SCIMED Life Systems, Inc.
One SCIMED Place
Maple Grove, Minnesota 55311

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

Classification Name: Catheter Guide Wire

Common or Usual Name: PTCA Guide Wire

Proprietary Name: SCIMED ChoICE PT Vision PTCA Guide Wires

II. Name of Predicate Devices:

<u>510(k) Reference No.</u>	<u>Predicate Device</u>
K943192 & K961015	SCIMED ChoICE PTCA Guide Wire
K945129 & K961015	SCIMED ChoICE Plus PTCA Guide Wire
K950113 & K961015	SCIMED ChoICE Exchange PTCA Guide Wire
K941895 & K960657	SCIMED ChoICE PT PTCA Guide Wire
K950216 & K960657	SCIMED ChoICE PT Plus PTCA Guide Wire
K950266 & K960657	SCIMED ChoICE PT Exchange PTCA Guide Wire
K960563	SCIMED Sceptor and Sceptor Exchange PTCA Guide Wire (Alternative Black PTFE Coating)



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III. Device Description:

The ChoICE PT Vision PTCA 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, Intermediate, Extra Support, Standard, Super Support, and Super Support II. The distal two centimeters of all models are straight shapeable or available in a pre-formed J-Tip.

The tapered, distal stainless steel core wire is surrounded by a polyurethane sleeve and is coated with ICE™ Hydrophilic Coating. The Floppy, Intermediate, Extra Support, and Standard guide wires will have the distal 38 centimeters surrounded by the polyurethane sleeve and are available in radiopaque lengths of 2 and 38 cm. The Super Support and Super Support II guide wires will have the distal 10 centimeters surrounded by the polyurethane sleeve, and are available in radiopaque lengths of 2 and 10 cm. The proximal wire is coated with polytetrafluoroethylene (PTFE)

IV. Intended Use:

The SCIMED ChoICE PT Vision PTCA 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 ChoICE PT Vision PTCA Guide Wires are not intended for use in the cerebral vasculature. The devices are provided sterile and intended for one procedure only.

V. Summary of Technological Characteristics:

The ChoICE PT Vision PTCA Guide Wires utilize the same materials and methods of construction as the currently marketed ChoICE and ChoICE PT family of Guide Wires.



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VI. Non-Clinical Test Summary:

Testing and evaluation of the guide wires included tip tensile, tip torsion, combined load, and tip flexibility. Additionally, J-Tip curve retention, polyurethane shear strength, torque response, and PTCA catheter compatibility were performed. Test results verified that the ChoICE PT Vision PTCA Guide Wires met all of the minimum requirements and are adequate for their intended use. The ChoICE PT Vision PTCA Guide Wires are considered to be substantially equivalent to guide wires currently marketed by SCIMED (ChoICE, and ChoICE PT Guide Wires) based on a comparison of intended use, design and the results of *in vitro* testing and evaluation.