

K960657

APR 29 1996

SECTION TWO
510(K) SUMMARY OF SAFETY AND EFFECTIVENESS
(Pursuant To Section 12 of the SAFE MEDICAL DEVICES ACT of 1990)
Prepared April 3, 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 Exchange
Extra Support PTCA Guide Wire

SCIMED ChoICE™ PT Exchange
Extra Support Long Taper PTCA Guide Wire

SCIMED ChoICE™ PT Plus
Extra Support PTCA Guide Wire

SCIMED ChoICE™ PT Plus
Extra Support Long Taper PTCA Guide Wire

SCIMED ChoICE™ PT
Extra Support PTCA Guide Wire

SCIMED ChoICE™ PT
Extra Support Long Taper PTCA Guide Wire

II. Name of Predicate Devices:

SCIMED ChoICE™ PT Exchange PTCA Guide Wire
SCIMED ChoICE™ PT Plus PTCA Guide Wire
SCIMED ChoICE™ PT PTCA Guide Wire

III. Device Description:

The ChoICE PT, ChoICE PT Plus, and ChoICE PT Exchange Extra Support and Extra Support Long Taper PTCA Guide Wires are steerable guide wires available in nominal diameters of 0.014 inches and nominal lengths of 190, 182 and 300 centimeters. The magnetic proximal section of the 182 cm length is designed to facilitate exchange of devices when used with SCIMED's Magnet Exchange Device. The 300 cm length allows exchange of therapeutic devices without the use of other exchange devices, e.g., docking systems or extension wires. The distal 35 centimeters on the entire ChoICE PT family of guide wires contains a stainless steel core wire that is jacketed with a radiopaque polymer and coated with ICE™ Hydrophilic Coating. The distal two centimeters of the guide wire are straight shapeable or available in a pre-formed J-Tip. The proximal wire is coated with either polytetrafluoroethylene (PTFE) or fluorinated ethylene propylene (FEP). The distal core wire tapers have increased in thickness or length to differentiate the Extra Support and Extra Support Long Taper models from the ChoICE PT, ChoICE PT Plus, and ChoICE PT Exchange Guide Wires. The Extra Support designates a taper of 2.25 inches proximal to the distal tip, whereas the Extra Support Long Taper designates a taper of 3.5 inches proximal to the distal tip. The ChoICE PT, ChoICE PT Plus and ChoICE PT Exchange Extra Support and Extra Support Long Taper Guide Wires will be provided sterile and are intended for one procedure use only (disposable).

IV. Intended Use:

The SCIMED ChoICE PT, ChoICE PT Plus and ChoICE PT Exchange Extra Support and Extra Support Long Taper 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, ChoICE PT Plus and ChoICE PT Exchange Extra Support and Extra Support Long Taper 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, ChoICE PT Plus and ChoICE PT Exchange Extra Support and Extra Support Long Taper PTCA Guide Wires utilize the same materials and methods of construction as the currently marketed ChoICE PT, ChoICE PT Plus and ChoICE PT Exchange PTCA Guide Wires. The only difference is the increase in thickness or length of the core wire tapers proximal to the tip.

VI. Non-Clinical Test Summary:

Testing and evaluation of the guide wires included tip tensile, torsion, combined load, and flexibility. Additionally, torque response and J-Tip curve retention were determined. Test results verified that the ChoICE PT Exchange Extra Support and Extra Support Long Taper PTCA Guide Wires met all of the minimum requirements and are adequate for their intended use.

No additional testing was performed on the ChoICE PT and ChoICE PT Plus Extra Support and Extra Support Long Taper models as a result of their identical distal design.

The ChoICE PT, ChoICE PT Plus and ChoICE PT Exchange Extra Support and Extra Support Long Taper PTCA Guide Wires are considered to be substantially equivalent to guide wires currently marketed by SCIMED (ChoICE PT, ChoICE PT Plus and ChoICE PT Exchange Guide Wires) based on a comparison of intended use, design and the results of *in vitro* testing and evaluation.