

**SCIMED**<sup>®</sup>  
Boston Scientific Corporation

SCIMED Life Systems, Inc.  
One SCIMED Place  
Maple Grove, MN 55311-1566  
612-494-1700

K905003

MAR - 4 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

December 13, 1996

---

### Device Name

#### Proprietary Names

SCIMED ChoICE Plus PTCA Guide Wires  
SCIMED ChoICE PT Plus PTCA Guide Wires  
SCIMED 182 cm ChoICE PT Vision PTCA Guide Wires

#### Common or Usual Name

PTCA Guide Wire

#### Classification Name

Catheter Guide Wire (per 21CFR 870.1330)

---

Continued on next page.



SCIMED Life Systems, Inc.

**Summary of Safety and Effectiveness, Continued**

**Section 6**

**Substantial  
 Equivalence  
 Comparison**

The modified proximal section on the ChoICE Guide Wires is substantially equivalent to the proximal section on the following SCIMED products.

<b>Product</b>	<b>510(k)</b>	<b>Clearance Date</b>
ChoICE Plus	K945129	March 3, 1995
	K961015	May 15, 1996
	K964551	Submitted November 14, 1996
ChoICE PT Plus	K950216	June 22, 1995
	K960657	April 29, 1996
EnTre III (marketed as the Sceptor Guide Wire)	K942333	August 31, 1994
	K946240	March 31, 1995
	K950534	April 28, 1996
	K960563	April 29, 1996
EnTre II	K931514	June 25, 1993
	K935022	January 18, 1993
	K935577	November 17, 1993
182 cm ChoICE PT Vision	K962572	Submitted July 1, 1996.

**Proximal  
 Section  
 Description**

The proximal section of the guide wire consists of a differential magnetic (Hiperco®) core wire encased in a FEP or PTFE coated stainless steel hypotube. The Hiperco® core wire/hypotube assembly is attached to the distal stainless steel core wire assembly by means of a weld and an adhesive bond. There are no other changes being made to the proximal section of the guide wires.

Continued on next page.



SCIMED Life Systems, Inc.

---

## Summary of Safety and Effectiveness, Continued

## Section 6

---

### Intended Use

The SCIMED ChoICE Plus, ChoICE PT Plus and the 182 cm ChoICE PT Vision 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 Plus, ChoICE PT Plus and the 182 cm ChoICE PT Vision 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 modified proximal section on the ChoICE Guide Wires utilize the same materials and methods of construction as the proximal section on the ChoICE Plus, ChoICE PT Plus, EnTre III, EnTre II, and the recently submitted 182 cm ChoICE PT Vision Guide Wires. The modification to the proximal section consists of an alternative manufacturing method for attaching the proximal Hiperco® core wire/hypotube assembly.

---

### Non-Clinical Test Summary

Testing and evaluation of the guide wires included

- Proximal Tensile,
- Joint Kink, and
- Fatigue testing.

#### Results

Test results verified that the modified proximal section of the ChoICE Guide Wires met all of the minimum requirements and is adequate for its intended use.

#### Summary

The modified proximal section of the ChoICE Guide Wires is substantially equivalent to the proximal section on the ChoICE Plus, ChoICE PT Plus, EnTre III, EnTre II, and the recently submitted 182 cm ChoICE PT Vision Guide Wire, based on a comparison of intended use, design and the results of *in vitro* testing and evaluation.

---