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K970244

MAR 28 1997

**Summary of Safety and Effectiveness**

**Appendix A**

**Submitter's Information**

Name and Address

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Maple Grove, Minnesota 55311

Contact Person

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Date

January 21, 1997

**Device Name**

Proprietary Name

SCIMED ChoICE PTCA Guide Wire  
SCIMED ChoICE Plus PTCA Guide Wire  
SCIMED ChoICE Exchange PTCA Guide Wire

Common or Usual Name

PTCA Guide Wire

Classification Name

Catheter Guide Wire

Continued on next page.



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**Summary of Safety and Effectiveness, continued** **Appendix A**

**Predicate Devices:**

The following predicate devices are available from SCIMED.

<b>Product</b>	<b>510(k)</b>	<b>Clearance Date</b>
ChoICE	K943192	November 22, 1994
	K950141	March 3, 1995
	K961015	May 15, 1996
	K964551	Submitted Nov. 14, 1996
ChoICE Plus	K945129	March 3, 1995
	K961015	May 15, 1996
	K964551	Submitted Nov. 14, 1996
	K965023	Submitted Dec. 17, 1996
ChoICE Exchange	K950113	March 31, 1995
	K961015	May 15, 1996
	K964551	Submitted Nov. 14, 1996
ChoICE PT	K941895	May 24, 1996
	K950835	May 25, 1995
	K960657	April 29, 1996
ChoICE PT Plus	K950216	June 22, 1995
	K960657	April 29, 1996
	K965023	Submitted Dec. 17, 1996
ChoICE PT Exchange	K950266	April 14, 1996
	K960657	April 29, 1996

**Device Description**

The ChoICE Guide Wires are steerable guide wires available in a nominal diameter of 0.014 inches and two tip configurations, straight shapeable and pre-formed J-Tip. The available tip flexibilities are

- Floppy,
- Intermediate,
- Extra Support,
- Standard,
- Super Support, and
- Super Support II



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## Summary of Safety and Effectiveness, continued

## Appendix A

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### Device Description continued

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 guide wires are

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

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### Intended Use

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

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### Summary of Technological Characteristics

The modified ChoICE Guide Wires utilize the same materials and methods of construction as the currently marketed ChoICE Family of Guide Wires and the ChoICE PT Family of Guide Wires. The change consists of a modification to the core wire dimensions.

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### Non-Clinical Test Summary

Additional testing of the modified ChoICE Extra Support Guide Wires was not performed since the identical core wire dimension is present on the ChoICE PT Extra Support Guide Wires.

Testing presented in K960657, ChoICE PT Extra Support on the first support diameter is directly applicable to the ChoICE Extra Support because of the identical design in this section of the wire.

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