

**MAY 15 1996**

**K961015**

**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 March 12, 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™ PTCA Guide Wire  
SCIMED ChoICE™ Plus PTCA Guide Wire  
SCIMED ChoICE™ Exchange PTCA Guide Wire

**II. Name of Predicate Devices:**

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

**III. Device Description:**

The ChoICE, ChoICE Plus, and ChoICE Exchange PTCA 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 four tip flexibilities available will be Floppy, Intermediate, Standard, and Extra Support. 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 will be ChoICE-190 cm, ChoICE Plus-182 cm and ChoICE Exchange-300 centimeters.

**IV. 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 Wire family is 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 modified ChoICE, ChoICE Plus, and ChoICE Exchange PTCA Guide Wires utilize the same materials and methods of construction as the currently marketed ChoICE, ChoICE Plus, and ChoICE Exchange PTCA Guide Wires. The modifications consist of a formulation change to the distal polyurethane material, and an alternative manufacturing method for attaching the proximal end of the spring coil.

**VI. Non-Clinical Test Summary:**

Testing and evaluation of the guide wires included ICE lubricious coating adherence, polyurethane shear strength, polyurethane adherence, and proximal spring coil joint shear testing. In addition, shelf life testing was performed on test units with the modified polyurethane material. Test results verified that the modified ChoICE, ChoICE Plus, and ChoICE Exchange met the design requirements and are adequate for their intended use. The modified ChoICE, ChoICE Plus, and ChoICE Exchange are considered to be substantially equivalent to the ChoICE, ChoICE Plus, and ChoICE Exchange guide wires currently marketed by SCIMED, based on a comparison of intended use, design and the results of *in vitro* testing and evaluation.

*Torque testing also performed.*