K961280 MAY 15 1996

SECTION 3
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 April 2, 1996

I. General Provisions:

Submitter's Name and Address:	SCIMED Life Systems, Inc. One SCIMED Place Maple Grove, Minnesota 55311
Contact Person:	Angela Raun (612) 494-2456
Classification Name:	Similar to Diagnostic Intravascular Catheters (21CFR Part 870.1200)
Common or Usual Name:	Coronary Guide Catheter
Proprietary Name:	SCIMED® 6,7,8,9 and10 French TRIGUIDE® Guide Catheters

II. Name of Predicate Devices:

SCIMED® 6,7,8,9 and10 French TRIGUIDE® Guide Catheters, and Cordis® Corporation Vista Brite Tip™ Guide Catheter

III. Device Description:

The modified 6F-10F SCIMED guide catheter shafts consist of three layers: 1) the inner polytetrafluoroethylene (PTFE) layer that provides a low coefficient of friction and facilitates easy passage of medical devices such as balloon dilatation catheters, guide wires or other therapeutic devices, 2) the middle layer which is made of braided stainless steel wire that extends from the shaft to the tip to provide torque control and support and 3) the outer layer, manufactured from Pebax®, which provides stiffness, memory and radiopacity. The distal tip is made of Pebax and is radiopaque. The tip is heat fused to the distal end of the shaft. The catheters utilize a one piece Pebax hub/strain relief that is molded to the proximal end of the guide catheter shaft. The devices will be provided sterile and are intended for one procedure use only.

IV. Intended Use:

The SCIMED guide catheters are designed to provide a pathway through which medical instruments, such as balloon dilatation catheters, guide wires or other therapeutic devices may be introduced. These devices are not intended for use in the cerebral vasculature.

V. Summary of Technological Characteristics:

The modified 6-10 French guide catheters are identical to SCIMED's currently marketed 6-10 French guide catheters with the one exception being that the catheter's inner fluoropolymer liner is composed of polytetrafluoroethylene (PTFE) instead of fluorinated ethylene propylene (FEP).

VI. Non-clinical Test Summary:

Functional testing consisted of pressure burst, material adhesion and device passage testing. Test results verified that the modified catheter with the PTFE inner liner is adequate for its intended use. The modified SCIMED 6-10 French guide catheters are considered substantially equivalent to guide catheters currently marketed by SCIMED and Cordis based on a comparison of intended use, the design and the results of *in-vitro* testing and evaluation.