

Schneider (USA) Inc
Pfizer Hospital Products Group
5905 Nathan Lane
Minneapolis, MN 55442
Tel 612 550 5500 Fax 612 550 5771

K961999

NOV 19 1996



SCHNEIDER

510(k) Summary for
SCHNEIDER GUIDER Softip® guiding catheter

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92. The assigned 510(k) number is K961999

Date Prepared: May 21, 1996

Sponsor: Schneider (USA) Inc
5905 Nathan Lane
Plymouth, MN 55442
Phone: (612)550-5500

Contact: Maria Brittle
Sr. Regulatory Affairs Specialist

Trade/Proprietary Name: SCHNEIDER GUIDER Softip® guiding catheters
Classification: Class II
Equivalent Devices Petite brite tip® guiding catheter (6 FR)
Vista brite tip™ guiding catheter (10 FR)
TRIGUIDE® guiding catheter (10 FR)
DVI guiding catheter (10 FR)
SOLID-7 guiding catheter (packaging only)

Device Description

The SCHNEIDER GUIDER guiding catheter is manufactured in five French sizes (6 through 10 FR) and multiple distal stem configurations and lengths. In addition, within each French size, catheters will be offered with differing handling characteristics to allow flexibility in meeting physician preferences.

Intended Use

The SCHNEIDER GUIDER Softip® guiding catheter is designed for the intravascular introduction of interventional devices.

Technological Characteristics

The following invitro performance tests were conducted with the SCHNEIDER GUIDER Softip® guiding catheters and approved predicate devices to show equivalence: bond strength tests, flexural rigidity, bodystock force delay, tip shape recovery, introducer resistance, inner liner ubricity, flow rate, pressure injection/leak test, output input torque to failure. Materials equivalence was demonstrated through biocompatibility testing following ISO 10993-1 recommendations.

The results of these tests indicated that the SCHNEIDER GUIDER Softip® guiding catheters are equivalent to the previously approved predicate devices and are, therefore, safe for the intended use.