

K98143

MAY 13 1998

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 _____.

Date Prepared: April 15, 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 SCHNEIDER GUIDER® Softip® guiding catheters

Device Description

The SCHNEIDER GUIDER® guiding catheter is manufactured in four French sizes (6 through 9 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 equivalence of the SCHNEIDER GUIDER® Softip® guiding catheter with new stem material was demonstrated through comparison of design with the original and summary of the design control activities undertaken to verify equivalence of the added material. Testing included biocompatibility, tip tensile pull, pressure injection leak test and shape recovery.

The results of design control activities indicated that the modified SCHNEIDER GUIDER® Softip® guiding catheters are equivalent to the currently marketed SCHNEIDER GUIDER® Softip® guiding catheters and are, therefore, safe for the intended use.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 13 1998

Ms. Marie Brittle
Sr. Regulatory Affairs Specialist
Schneider (USA) Inc.
Pfizer Hospital Products Group
5905 Nathan Lane
Minneapolis, MN 55442

Re: K981413
Trade Name: SCHNEIDER GUIDER® Softip® Guiding Catheters
Regulatory Class: II
Product Code: DQY
Dated: April 17, 1998
Received: April 20, 1998

Dear Ms. Brittle:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

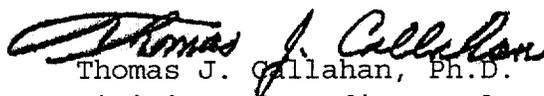
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your pre-market notification submission does not affect any obligation you might have

under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Thomas J. Callahan, Ph.D.
Division of Cardiovascular,
Respiratory and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):

Device Name: SCHNEIDER GUIDER® Softip® Guiding Catheter

Indications for Use:

The SCHNEIDER GUIDER® Softip® Guiding Catheter is designed for the intravascular introduction of interventional devices.



DIVISION OF (S) (U)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number: K981413

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)