AUG 1 1 1998

K980453

510(k) Summary

Date Prepared August 7, 1998

Submitter

Address: Schneider (USA) Inc
5905 Nathan Lane
Minneapolis, MN 55442

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Contact Person

Ronald W. Bennett
Senior Regulatory Affairs Specialist

Device Name and Classification

Trade Name: SCHNEIDER GUIDER Softip® Guiding Catheters

Classification: Class II

Predicate Devices

SCHNEIDER GUIDER Softip® Guiding Catheters (K961999)
Cordis Vista brite tip™ guiding catheter

Device Description

The SCHNEIDER GUIDER Softip® Guiding Catheter in this 510(k) is available in four French sizes (6 through 9 Fr) with multiple distal stem configurations and lengths. SCHNEIDER GUIDER Softip® Guiding Catheters are designed for the introduction of interventional devices.

Indication

SCHNEIDER GUIDER Softip® Guiding Catheters are intended to facilitate the placement of interventional devices into the peripheral and coronary systems and, in addition for the XF models, into the neurovascular system.

Technological Characteristics

The design of the SCHNEIDER GUIDER Softip® Guiding Catheter remains the same as for the previous cleared devices. These have been tested in simulated aortic and carotid anatomy with appropriate interventional devices to test that the force needed for insertion is acceptable.

Summary

In summary Schneider (USA) Inc has demonstrated that the SCHNEIDER GUIDER Softip® Guiding Catheters are substantially equivalent based on design, test results, and indications for use to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 1 1998

Mr. Ronald W. Bennett
Schneider (USA) Inc.
Pfizer Medical Technology Group
5905 Nathan Lane
Minneapolis, MN 55442

Re: K980453
SCHNEIDER GUIDER Softip® Guiding Catheter
Regulatory Class: II (two)
Product Code: 74 DQY
Dated: May 26, 1998
Received: May 28, 1998

Dear Mr. Bennett:

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 (Premarket 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 premarket 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) 594-4648. 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"(21 CFR 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

Thomas J. Callahan, Ph.D.
Director
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 Catheters are designed for the introduction of interventional devices. They are intended to facilitate the placement of interventional devices into the peripheral and coronary systems and, in addition for the XF models, into the neurovascular system.

Tara A. Price

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K980453

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)