

K982077

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

AUG 11 1998



510(K) SUMMARY



Date Prepared: June 12, 1998

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

Contact: Janell A. Colley
Regulatory Affairs Specialist

Trade/Proprietary Name: 4 French SELECTOR™ diagnostic catheter

Classification: Class II

Equivalent Devices 5 French and 6 French SELECTOR™ diagnostic catheters
(March 3, 1993: K925522/March 29, 1996: K960801)
4 French SUPER TORQUE and SUPERTORQUEPLUS™
diagnostic catheter (April 2, 1996: K960975).

Device Description The 4 French SELECTOR™ diagnostic catheter is
manufactured in multiple lengths and with multiple distal
stem configurations.

Intended Use The 4 French SELECTOR™ is designed to deliver contrast
medium during angiography as well as to provide a conduit
for various diagnostic and therapeutic procedures.

Technological Characteristics

The following tests were performed on the 4 French SELECTOR™ diagnostic catheter and on the predicate device to show equivalence: bond strength tests, flexural rigidity, bodystock force decay, shape recovery, flow rate, dynamic pressure, and output/input torque to failure testing.

The results of these tests indicate that the 4 French SELECTOR™ diagnostic catheter is equivalent to the previously approved predicate device and is therefore safe for its intended use.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 11 1998

Ms. Janell A. Colley
Schneider (USA) Inc.
Pfizer Medical Technology Group
5905 Nathan Lane
Minneapolis, MN 55442

Re: K982077
4 French SELECTOR™ Diagnostic Catheter
Regulatory Class: II (two)
Product Code: 74 DQO
Dated: June 12, 1998
Received: June 12, 1998

Dear Ms. Colley:

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.

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

Enclosure

INDICATIONS FOR USE

510(k) Number (if known):

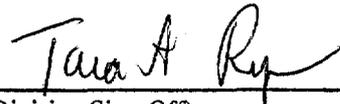
Device Name: 4 French SELECTOR™ diagnostic catheter

Indications for Use:

The 4 French SELECTOR™ diagnostic catheter is designed to deliver contrast medium during angiography as well as to provide a conduit for various diagnostic and therapeutic procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number K982077

Prescription Use
(Per 21 CFR 801.109)

or **Over-The-Counter Use**

(Optional Format 1-2-96)