OCT 21 1998

## 10 510(k) Summary for the SCHNEIDER Docking-Extension Wire

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 K982592.

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| **Date prepared:** | **July 21, 1998** |
| **Sponsor:** | **SCHNEIDER (Europe) GmbH**<br>**Ackerstrasse 6**<br>**CH-8180 Bülach**<br>**Switzerland** |
| **Contact:** | **Thomas Thaler, Ph. D.**<br>**Director, Clinical and Regulatory Affairs** |
| **Trade/Proprietary Name:** | **Docking-Extension Wire** |
| **Classification:** | **Class II** |
| **Predicate Device:** | **ACS DOC™ Extension Wire** |

**Device Description:**

The SCHNEIDER Docking-Extension Wire is used to elongate the working length of compatible SCHNEIDER extendable guide wires. The stainless-steel Docking-Extension Wire has an outer diameter of 0.014" (0.36 mm) and a length of 130 cm. Its distal end bears a preformed superelastic connecting hypotube. This superelastic property allows the proximal end of the guide wire to be fixed in the hypotube to such an extent, that axial forces can easily be transmitted. A docking aid enables easy introduction of the extendable end of the guide wire into the hypotube. The device is compatible with the SCHNEIDER extendable guide wires (C-Thru, Hannibal and Clyde). The currently marketed guide wires had been slightly modified at the proximal end to create a tapered end in order to be accommodated into the hypotube of the Docking-Extension Wire. This modification does not in any way affect the safety or performance of the guide wire.

**Technological Characteristics:**

Equivalence in technological characteristics was substantiated by comparative performance testing including docking joint tensile strength, docking junction fatigue and glued bond break load, and compatibility with interventional devices. Biocompatibility testing of the Docking-Extension Wire was conducted with regard to cytotoxicity, coagulation, indirect hemolysis, intracutaneus reactivity, systemic toxicity and sensitization.

The results of all testing indicated that the SCHNEIDER Docking-Extension Wire is equivalent to the ACS DOC™ Extension Wire and is, therefore, safe for the intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 21 1998

Thomas Thaler, Ph.D.
SCHNEIDER (Europe) GmbH
Ackerstrasse 6
CH-8160 Bülach
Switzerland

Re: K982592
Docking-Extension Wire
Regulatory Class: II (two)
Product Code: DQX
Dated: July 22, 1998
Received: July 24, 1998

Dear Dr. Thaler:

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, 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: **Docking-Extension Wire**

Indications for Use: **The Docking-Extension Wire is intended for extension of the working length of an already introduced guide wire when exchanging over-the-wire interventional devices during an angioplasty procedure.**

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, [illegible],
and Neurological Devices
510(k) Number K982592