

K970528

JUN 10 1997

510(k) Summary for  
Clyde Coronary Guidewire

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:** February 10, 1997

**Sponsor:** **Schneider (Europe) AG**  
Ackerstrasse 6  
PO Box CH-8180  
Bulach, Switzerland

**Contact:** **Rudolf Ott**  
**V.P. Clinical and Regulatory Affairs**  
**Phone: 011-411-8721179**

**Trade/Proprietary Name:** Clyde Coronary Guidewire  
**Classification:** Class II  
**Equivalent Devices** C-Thru Coronary Guidewire

**Device Description**

The Clyde Coronary Guidewire is a 0.014" guidewire manufactured in lengths of 100-400 cm. The guidewire is made of a stainless steel, PTFE coated proximal shaft, which tapers down to a flexible distal tip. The tip area consists of a radiopaque tungsten spring coil. The distal 3 cm of the coil are very flexible and shapeable.

**Intended Use**

The Clyde Coronary Guidewire is intended to reach and cross, stenotic lesions prior to the insertion of a coronary balloon dilation catheter.

**Technological Characteristics**

Equivalence in technological characteristics was substantiated by a detailed comparison of the Clyde and C-Thru coronary guidewire design and materials. Because of the similarity in materials a reduced biocompatibility battery, consisting of hemolysis and cytotoxicity, was conducted.

The results of these comparisons indicated that the Clyde coronary guidewire is equivalent to the C-Thru coronary guidewire and is, therefore, safe for the intended use.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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Mr. R. Ott  
Vice-President Clinical and Regulatory Affairs  
Schneider (Europe) AG  
Pfizer Hospital Products Group  
Ackerstrasse 6, P.O. Box CH-8180  
Bulach/Switzerland

Re: K970528  
CLYDE™ Coronary Guidewire  
Regulatory Class: II (two)  
Product Code: DQX  
Dated: May 26, 1997  
Received: May 28, 1997

Dear Mr. Ott:

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 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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.

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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 at (301) 443-6597.

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

