

510(k) Summary for
HANNIBAL™ Guidewire

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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 K970494.

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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: HANNIBAL™ Guidewire
Classification: Class II
Equivalent Devices: ACS Hi-Torque Extra S'port™ Guidewire (performance)
C-Thru Coronary Guidewire (materials, sterilization, packaging)

Device Description

The HANNIBAL™ Guidewire is a 0.014" guidewire manufactured in lengths of 185-315 cm. The guidewire is made of stainless steel, PTFE coated proximal shaft, which tapers down to a flexible distal tip. The tip area consists of a radiopaque tungsten spring coil, which is attached to the distal flexible shaft port and soldered to the proximal taper of the shaft. The distal part of the coil is very flexible and shapeable.

Intended Use

* The HANNIBAL™ steerable guide wires are designed to reach and cross stenotic lesions prior to the insertion on a coronary balloon dilatation catheter.

* Schneider steerable stent support guide wires are also designed to reach and cross stenotic lesions prior to the insertion of a coronary balloon dilatation catheter with mounted expandable stent, or of a stent delivery device.

* Any use other than that intended is not recommended.

Technological characteristics

Equivalence in technological characteristics was substantiated by comparative performance testing including bond strength, tip flexibility, coating adhesion, torque and compatibility with interventional devices. Because materials used were the same as those used in other Schneider guidewires, a reduced biocompatibility battery, consisting of hemolysis and cytotoxicity, was conducted.

The results of all testing indicated that the HANNIBAL™ guidewire is equivalent to the ACS Hi-Torque Extra S'port™ guidewire and is, therefore, safe for the intended use.