JUN 26 1996

K961232

# 510(K) Summary

| | |
|---|---|
| Submitter's Name: | Biocompatibles Limited<br>Brunel Science Park<br>Kingston Lane<br>Uxbridge<br>Middlesex UB8 3PQ<br>England<br>Tel. +44 1895 274481 |
| Contact Person: | Mr. Neil McLachlan<br>Regulatory Affairs Manager |
| 510(k) Summary Date: | March 29, 1996 |
| Device Names: | 0.014" Floppy Guide Wire with Phosphorylcholine Polymer (PCP) Coating and 4 cm Radiopaque Tip and 0.014" Intermediate Guide Wire with Phosphorylcholine Polymer (PCP) Coating and 4 cm Radiopaque Tip |
| Common Name: | Guide Wire |
| Classification Name: | Catheter Guide Wire (21 CFR 870.1330) |
| Predicate Devices: | Advanced Cardiovascular Systems, Inc. 0.014" Hi-Torque Floppy II® Guide Wire and 0.014" Hi-Torque Intermediate® Guide Wire |

Device Description:

The Floppy and Intermediate guide wires have a nominal outside diameter of 0.014 inch measured at the distal spring coil. The guide wires are 176 cm long (nominal) and have a distally attached 30 cm composite spring coil. The most distal 4 cm of the spring coil is radiopaque. The core wire and spring coils, up to and including the tip, are coated with PCP.

Intended Use:

The Floppy and Intermediate guide wires and predicate devices are intended for use to facilitate the placement of PTA and/or PTCA balloon dilatation catheters within the peripheral or coronary vasculature. The guide wires are designed for safe use with appropriately sized balloon catheters. The guide wires are not intended for use in the cerebral vasculature.

Comparison of Technological Characteristics:

The 0.014" Floppy and Intermediate Guide Wires with PCP Coating and 4 cm Radiopaque Tip have similar technological characteristics as the predicate devices. The BCP and ACS guide wires are similar in design, materials, intended use, and sterilization.

The BCP and ACS 0.014" guide wires have a stainless steel core wire that is taper ground distally to improve flexibility. The two BCP guide wires and the ACS Intermediate guide wire have a full length core wire. The distal tip section of each style BCP guide wire is flattened to increase tip section flexibility. The ACS Intermediate guide wire has a round core wire passing into the middle joint and continuing on to the tip. The ACS Floppy guide wire core terminates just past the middle joint. A stainless steel flat ribbon connects the middle joint and stainless steel tip.

A 30 cm (nominal) composite spring coil is concentrically positioned over the distal core wire or shaping ribbon of each guide wire. The proximal 26 cm (nominal) of BCP and ACS spring coils are made of stainless steel spring wire. Each manufacture has made the distal 3 - 4 cm of spring coil radiopaque through the use of platinum/tungsten spring coils. The BCP spring coil is formed at a joint proximal to the traditional middle joint and the spring coils are not attached to the core wire at this point. For both BCP and ACS guide wires, the spring coils are brazed (BCP) or soldered (ACS) to the central core wire at a joint proximal to the tip. For all guide wires, the tip section is shapeable.

The core wire and entire length of spring coil of the BCP guide wires are coated with PCP. The ACS guide wires have a Teflon coated core wire. The ACS spring coil proximal to the middle joint is coated with a silicone-based material (Microglide®) and the coil distal to the middle joint is uncoated.

Packaging and Sterilization

The BCP guide wires are individually packaged in a lacquered paper and polyester-polypropylene composite plastic heat sealable pouch. The ACS product is packaged in Tyvek/Mylar heat sealable pouch. Both guide wire providers sterilize the product with ethylene oxide gas. The shelf life of the BCP guide wires is one year. The one year shelf life for the BCP guide wires was established following real-time aging. The shelf life of the ACS products is two years.

Safety and Effectiveness:

In vitro performance testing was conducted according to the guidelines presented in FDA's January 1995 Coronary and Cerebrovascular Guidewire Guidance. The performance of BCP Floppy and Intermediate guide wires and ACS guide wires was

compared by bench testing. The BCP Floppy and Intermediate guide wires were found to have adequate tensile strength, torque strength, torqueability, and tip flexibility. The biocompatibility tests conducted included Acute Systemic Toxicity, Skin Irritation, Skin Sensitization, Cytotoxicity, Hemolysis, and LAL Pyrogenicity. The PCP-coated guide wires are non-toxic and biocompatible for short term use in the vascular system.

Based on the indications for use, design and construction, and results of the bench and biocompatibility testing, the Biocompatibles 0.014" Floppy and Intermediate Guide Wires with PCP Coating and 4 cm Radiopaque Tip are safe and effective for their intended use.