K962266 SEP 10 1996

510(K) Summary

Submitter's Name: Biocompatibles Cardiovascular, Inc.
1049 Kiel Court
Sunnyvale, CA 94089
Tel: (408) 747-0200
Fax: (408) 747-1171

Contact Person: Mr. James Wood
Chief Engineer

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Device Names:

1. 0.014" Floppy Extra Long Guide Wire with Phosphorylcholine (PC) Polymer Coating and 30 cm Radiopaque Tip
2. 0.014" Intermediate Extra Long Guide Wire with Phosphorylcholine (PC) Polymer Coating and 30 cm Radiopaque Tip
3. 0.014" Floppy Extra Long Guide Wire with Phosphorylcholine (PC) Polymer Coating and 4 cm Radiopaque Tip
4. 0.014" Floppy Extra Long Guide Wire with Phosphorylcholine Polymer Coating and 4 cm Radiopaque Tip

Common Name: Guide Wire

Classification Name: Catheter Guide Wire (21 CFR 870.1330)

Predicate Devices: Biocompatibles 0.014" Floppy and Intermediate Guide Wires with Phosphorylcholine Polymer Coating (K955135 - SE Determination on April 9, 1996)

Device Description:

The Floppy (2) and Intermediate (2) Extra Long Guide Wires have a nominal outside diameter of 0.014 inch measured at the distal spring coil. The guide wires are 300 cm (nominal) in length and have a distally attached 30 cm composite spring coil. For the 30 cm radiopaque guide wires, the entire spring coil is made of platinum/tungsten alloy. The spring coil of the 4 cm radiopaque guide wires is proximally made of stainless steel wire (26 cm) and has a distal platinum/tungsten alloy spring coil for opacity. For all guide wires, the core wire and spring coils, up to and including the tip, are coated with phosphorylcholine polymer.

Intended Use:

The Floppy and Intermediate Extra Long Guide Wires 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 Extra Long Guide Wires with PC polymer coating are similar to the predicate guide wires. The subject guide wires and predicate guide wires are manufactured by the same company. The 30 cm spring coils and coil assembly with the core wire are identical between the predicate devices and two subject guide wires. The only difference between these two groups of wires is the overall length (175 cm vs 300 cm).

The remaining two 0.014" Floppy and Intermediate Extra Long Guide Wires have a 4 cm radiopaque alloy distal spring coil brazed to a 26 cm proximal stainless steel spring coil. The 4 cm radiopaque guide wires have one more joint than the predicate guide wires. The 4 cm guide wire core wire specifications are identical to the predicate device, with the exception of the additional 125 cm of length.

The predicate and four extra long guide wires have a stainless steel core wire that is taper ground distally to improve flexibility. The guide wires each have a full length core wire extending to the tip. The distal tip section of each guide wire is flattened to increase tip section flexibility and facilitate shapeability. Differences in tip section flexibility are made possible by changing the amount of taper in the core wire, distally, and the length of the flattened section between the second to last joint and tip joint. The core wire and entire length of spring coil of the guide wires are coated with PC polymer.

Packaging and Sterilization

The predicate and subject guide wires are packaged in the same materials and ethylene oxide sterilized by the same contract sterilizer. The guide wires are individually packaged in a lacquered paper and polyester-polypropylene composite plastic heat sealable pouch. The shelf life of the guide wires is one year. The one year shelf life for the guide wires was established following real-time aging.

Safety and Effectiveness:

In vitro performance testing of the predicate devices was conducted according to the guidelines presented in FDA's January 1995 Coronary and Cerebrovascular

Guidewire Guidance. 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 PC polymer-coated guide wires are non-toxic and biocompatible for short term use in the vascular system. Bench performance and biocompatibity testing was not performed on the subject guide wires; there is no reason to believe the subject guide wires would yield dissimilar results.