K970938

510(k) Summary

Submitter's Name:	Biocompatibles Cardiovascular Inc. 680 West Maude Avenue, Suite 2 Sunnyvale, CA 94086 USA
Contact Person:	John P. Yianni, Ph.D. Technical Director
510(k) Summary Date:	October 20, 1997
Device Names:	Hunter 0.014 inch Super Soft and Hunter 0.014 inch Soft Guide Wires with PC Coating
Common Name:	Coronary and Peripheral Vascular Guide Wire
Classification:	Class II - Catheter Guide Wire (21 CFR 870.1330)
Predicate Device:	Medrad Inc. (K802473) • Benzalkonium-Heparin Coated Guidewires • Amplatz Heparin-Coated Wire Guide • Thrombo-Resistant Coated Spring Guide

NOV 17 1997

Device Description:

The Hunter guide wires are coated with a high molecular weight phosphorylcholine ("PC") polymer. The core wire and spring coils are coated with phosphorylcholine (PC). The PC coating aids in the prevention of thrombus formation on the guide wire tip during short-term clinical use. While the PC coating has been shown to resist thrombus accumulation during PTCA procedures, a clinical significance of this reduction has not been demonstrated. The guide wires are full-length core wire design having a distal 30cm long spring coil. PC-coated guide wires are available in 175cm and 300cm lengths with distal radiopaque platinum/tungsten spring coil lengths of 4cm and 30cm.

Intended Use:

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 0.014 inch size and designed for safe use within appropriately sized balloon catheters. The guide wires are not for use in the cerebral vasculature.

Comparison of Technological Characteristics:

The PC-solution is applied as a thin film, by dip coating, to the guide wire spring coil and core wire surfaces. A stable and durable polymer coating adheres to the otherwise hydrophobic substrate. Phosphorylcholine polar head groups on the surface are hydrophilic. Upon exposure to water or blood, PC molecules rapidly absorb water. The surface becomes lubricious and resistant to protein adsorption and cellular adhesion. The reduction of protein adsorption (e.g. fibrinogen) and decrease in platelet adhesion are fundamental characteristic of the PC coating. PC-coated surfaces are sterilizable by gamma radiation.

The benzalkonium-heparin (BH) coating solution is prepared from a precipitated heparin-quaternary ammonium complex (salt). The BH complex is applied to the guide wire by dip coating. The BH surface is hydrophobic rather than hydrophilic. The BH coating is soluble in water and, therefore, is easily leached from the surface over time. The recognized temporary protection against thrombus formation on BH-coated surfaces was considered adequate for most catheterization procedures.

Expression of the hydrophilic and blood compatible characteristics of PC-coated surfaces is dependent on the presence of water for hydration; no circulating protein cofactor is required. The predicate BH coating is significantly different from the PC-coating in that the heparin molecule is an indirect thrombin inhibitor and requires the presence of antithrombin III (ATIII) to complete the inhibition. The PC coating is inert to normal biochemical degradation processes. The fundamental differences between PC and BH coatings are the ability of the PC to reduce substrate clotting protein (fibrinogen) adsorption, resist platelet adhesion (and therefore activation and aggregation), and function independent of other cofactors (other than water).

Packaging and Sterilization

The PC-coated guide wires are packaged in Tyvek/Mylar heat sealed pouches and sterilized with gamma radiation. The package material of the BH-coated guide wires is also Tyvek/Mylar and the method of sterilization is ethylene oxide gas.

Safety and Effectiveness:

The effectiveness of PC-coated guide wires at reducing protein adsorption and thrombus formation was confirmed by *in vitro* and clinical studies, respectively. Fibrinogen binding to PC-coated surfaces was less than that to other common guide wire coating materials. Five different groups of coated guide wires, including PC-coated guide wires, used to perform 50 clinical PTCA procedures were examined by scanning electron microscopy. The results of the clinical study demonstrated the effectiveness of the PC coating to resist thrombus deposition under the variable conditions of clinical PTCA.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Nancy F. Teague
Consultant and Correspondent for
Biocompatibles Cardiovascular, Inc.
C.L. McIntosh Associates, Inc.
12300 Twinbrook Parkway, Suite 625
Rockville, Maryland 20852

Re: K970938
Hunter™ o.o14 inch Soft and Super
Soft Guide Wires with PC Coating
Regulatory Class: II (two)
Product Code: DQX
Dated: September 17, 1997
Received: September 18, 1997

Dear Ms. Teague:

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 (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/dsmamain.html".

Sincerely yours,

Thomas J. Callahan

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): K970938

Device Name: *Hunter*™ 0.014 inch Super Soft Guide Wire with PC Coating
and
Hunter™ 0.014 inch Soft Guide Wire with PC Coating

Indications for Use:

The *Hunter*™ Super Soft and Soft guide wires with phosphorylcholine (PC) coating are intended to facilitate the placement of PTA and/or PTCA balloon catheters within the peripheral and coronary vasculature. This guide wire is 0.014-inch size and designed for safe use within appropriately sized balloon catheters. This device is not for use in the cerebral vasculature.

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510(k) Number K970935

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801~109)

(Optional Format 1-2-96)