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K033500

JAN 2 9 2004

BD

Premarket Notification [510(k)] Summary of Safety and Effectiveness for BD Careflow™ Central Venous Catheters

Submitter:	Becton Dickinson Infusion Therapy Systems Inc.
Address:	9450 South State Street Sandy, UT 84070
Contact Person:	Leslie Wood, Manager, Regulatory Affairs
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Date Summary Prepared:	October 27, 2003
Trade Name:	BD Careflow™ Central Venous Catheter
Common Name:	Central Venous Catheter
Classification Name:	Intravascular Catheter
Predicate Device:	BD Hydrocath™ Central Venous Catheter

Product Description:

The BD Careflow™ Central Venous Catheter (CVC) is a polyurethane, radiopaque catheter. It is identical to the BD Hydrocath™ CVC except that the BD Careflow product does not have a hydrophilic coating.

The BD Careflow product line includes the same range of product offerings as the BD Hydrocath product line: 60-300mm lengths, 2.5-9.5 French sizes, and 1 – 5 lumens.

BD Careflow catheters are sold in convenience kit form containing components to facilitate catheter placement, such as a guidewire, introducer needle, introducer catheter, vessel dilator, syringe, injection caps, slide clamps, and movable suture wing. The kit components are identical to those that were provided in the BD Hydrocath CVC convenience kits.

Intended Use:

The BD Careflow™ Central Venous Catheter is an intravascular catheter that is introduced into a patient's vascular system for short-term use (less than 30 days) using an introducer and guidewire. The catheter is used to sample blood, monitor blood pressure, or administer fluids.

Technological Characteristics Comparison:

The design and technological characteristics are the same as those of the BD Hydrocath CVC product except that there is no hydrophilic coating on the BD Careflow CVC products.

Nonclinical Tests Support Substantial Equivalence:

Side-by-side testing of BD Careflow (modified) and BD Hydrocath (unmodified) devices was conducted to compare tensile strength, potential for leakage, and catheter stiffness.

Conclusions from Nonclinical Tests:

Data have been provided to demonstrate that product attributes are substantially equivalent between the modified and unmodified devices.

The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence found in the Federal Food, Drug, and Cosmetic Act, as amended and as applied under 21 CFR 807, Subpart E under which a device can be marketed without premarket approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to or in support of substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 9 2004

Becton Dickinson & Corporation
Ms Leslie Wood
Manager, Regulatory Affairs
Becton Dickinson Infusion Therapy Systems Incorporated
9450 South State Street
Sandy, Utah 84070

Re: K033500
Trade/Device Name: BD Careflow™ Central Venous Catheter
Regulation Number: 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: FOZ
Dated: November 4, 2003
Received: November 5, 2003

Dear Ms.Wood

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K033500

DEVICE NAME BD Careflow™ Central Venous Catheter

INDICATIONS FOR USE

The BD Careflow™ Central Venous Catheter is an intravascular catheter that is introduced into a patient's vascular system for short-term use (less than 30 days) using an introducer and guidewire. The catheter is used to sample blood, monitor blood pressure, or administer fluids.

Vida Hibbard, Interim Branch Chief
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K033500

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: X OR Over-The-Counter Use: _____
(per 21 CFR 801.109)