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Attachment D

BD

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Premarket Notification [510(k)] Summary

Submitter:	Becton Dickinson Infusion Therapy Systems Inc.
Address:	9450 South State Street Sandy, UT 84070
Contact Person:	Leslie Wood Manager, Regulatory Affairs
Telephone Number:	(801) 565-2504
FAX Number:	(801) 565-2749
Date Summary Prepared:	October 4, 2004
Trade Name:	BD OneCath™
Common Name:	Midline Catheter
Classification Name:	Intravascular catheter
Classification:	Class II 880.5200 FOZ
Predicate Device:	BD L-Cath Midline Catheter

Description of the BD OneCath Midline Catheter:

Device selection is an important component of intravenous therapy. Some of the patient considerations that are included in this decision are the: (1) length and type of therapy, (3) adequacy of venous access, (4) lifestyle and activity, and (5) setting in which therapy will be administered. BD OneCath midline catheters are 20 cm long, designed for peripheral use to sample blood, monitor blood pressure, or administer fluids, and prescribed when IV therapy is expected to last for 2-4 weeks. The basilic, cephalic and median cubital veins of the arm are the preferred locations for midline catheter insertion. The types of infusates recommended for midline catheters are the same as those recommended for shorter peripheral IV catheters.

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The BD OneCath midline products are similar in design to other midline catheters. The catheter tubing is a radiopaque, polyurethane material that is inserted into the vascular system via a catheter introducer.

Intended Use of the BD OneCath Peripherally Inserted Central Catheter:

The BD OneCath™ midline catheter is inserted into a patient's vascular system for short-term use (less than 30 days) to sample blood, monitor blood pressure, or administer fluids. This intravascular catheter may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness of procedure.

Technological Characteristics Comparison:

The polyurethane used for the BD OneCath product has improved radiopacity, resistance to alcohol, and flex endurance than the polyurethane used for the current L-Cath midline catheter. These improved characteristics will make the BD OneCath midline catheters more competitive in this market.

Nonclinical Tests Support Substantial Equivalence:

Biocompatibility testing of the new polyurethane tubing and physical testing on the areas of potential failure (such as pull strength and the security of junctions between the extension tubing and molded parts) were conducted.

Conclusions from Nonclinical Tests:

The BD OneCath midline catheter is substantially equivalent to the BD L-Cath midline catheter.

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

DEC - 3 2004

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

Re: K042862
Trade/Device Name: BD OneCath™ Midline Catheter
Regulation Number: 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: FOZ
Dated: October 13, 2004
Received: October 15, 2004

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 (240) 276-0115. 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

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Indications For Use

510(k) Number (if known): K042862

Device Name: BD OneCath™ Midline Catheter

Indications For Use:

The BD OneCath™ midline catheter is inserted into a patient's vascular system for short-term use (less than 30 days) to sample blood, monitor blood pressure, or administer fluids. This intravascular catheter may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness of procedure.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K042862