K050207
Page 1 of 2

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APR 7 2005

BD
Helping all people live healthy lives

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:	January 18, 2005
Trade Name:	BD Posiflow™ Positive Displacement Valve
Common Name:	Luer Activated Valve
Classification Name:	Accessory to an Intravascular Administration Set
Predicate Device:	BD Posiflow Positive Displacement Valve

Description of the BD Posiflow Positive Displacement Valve:

The BD Posiflow Positive Displacement Valve is a needleless alternative to an IV set injection port. It is accessed by a standard luer taper connection for continuous or intermittent infusion or the withdrawal of fluids. The positive displacement feature is intended to eliminate fluid retrograde, which normally results when disconnecting a connector from an IV injection site.

Intended Use of the BD Posiflow Positive Displacement Valve:

The BD Posiflow Positive Displacement Valve is an accessory to an intravascular administration set that permits injection, gravity flow or withdrawal of fluids. The BD Positive Displacement Valve can be used by itself or as a component on an extension/infusion set, a vial adapter, or as a connector to convert a standard access site to a needleless access site.

Technological Characteristics Comparison:

Modifications have been made to improve the reseal function of this device after removal of a luer connector. No changes were made to any materials.

Nonclinical Tests Support Substantial Equivalence:

The current and modified devices were compared for flow rate, backpressure leakage, and vacuum leakage.

Conclusions from Nonclinical Tests:

The current and modified BD Posiflow Positive Displacement Valves are substantially equivalent.

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

APR 7 2005

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

Re: K050207
Trade/Device Name: BD Posiflow Positive Displacement Valve
Regulation Number: 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: January 26, 2005
Received: January 28, 2005

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/industry/support/index.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

Indications For Use

510(k) Number (if known): K050207

Device Name: BD Posiflow Positive Displacement Valve

Indications For Use:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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 K050207