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K032843
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FEB 27 2004

Indispensable to human health

PREMARKET NOTIFICATION

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:	August 26, 2003
Trade Name:	BD Nexiva™ Closed IV Catheter System
Common Name:	Intravascular Catheter
Classification Name:	Intravascular Catheter
Predicate Devices:	BD Saf-T-Intima™ IV Catheter B. Braun Introcan® Safety™ IV Catheter

Description of the BD Nexiva™ Closed IV Catheter System:

The BD Nexiva Closed IV Catheter System consists of an over-the-needle, peripheral intravascular catheter made from Vialon™ polyurethane, integrated extension tubing with a Y adapter and clamp, BD Q-Syte™ luer access port, and a passive needle-shielding mechanism.

The design of the Nexiva IV catheter can be described as a closed system since it protects clinicians from blood exposure during the catheter insertion procedure. Since the needle is withdrawn through a septum that seals after the needle has been removed and both ports of the Y adapter are closed, blood is contained within the Nexiva device during catheter insertion. The pressure exerted on the needle as it passes through the septum wipes blood from the needle, further reducing potential blood exposure. The slide clamp on the integrated

extension tubing is provided to eliminate blood exposure when the vent plug is replaced with an infusion set connection or a BD Q-Syte luer access port.

Intended Use:

The Nexiva™ intravascular 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 intravascularly. The needle-shielding feature and luer access port aid in the prevention of needlestick injuries. Blood is contained within the device during the catheter insertion process aiding in the prevention of blood exposure. This catheter may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness of procedure.

The 18-24 gauge Nexiva catheters are suitable for use with power injectors rated for a maximum of 300 psi when the luer access port(s) is removed and a direct connection is made.

Technological Characteristics Comparison:

The Nexiva catheter is similar to the Saf-T-Intima catheter in that both have Vialon polyurethane catheters, notched needles, integrated extension tubing with Y adapters, removable access ports, and a closed system.

The Nexiva catheter is similar to the Introcan Safety catheter in that a variation in the needle circumference 'traps' the needle tip within a shield and both can be used with power injectors with a maximum pressure setting of 300 psi.

Nonclinical Tests Support Substantial Equivalence:

The Nexiva catheter is composed of materials that have been tested in accordance with ANSI/AAMI/ISO 10993-1 (1997).

The Nexiva and Introcan catheters were compared in a simulated use study.

Conclusions from Nonclinical Tests:

The Nexiva IV catheter is substantially equivalent to the Introcan device.

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

FEB 27 2004

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

Re: K032843
Trade/Device Name: BD Nexiva Closed IV Catheter System
Regulation Number: 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: FOZ
Dated: December 10, 2003
Received: December 11, 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

Becton Dickinson Infusion Therapy Systems Inc.
Sandy, UT 84070

K032843

INDICATIONS FOR USE

Device Proprietary Name: BD Nexiva™
Closed IV Catheter System

Device Classification Name: Intravascular Catheter (80 FOZ)

Indications for Use:

The Nexiva™ intravascular 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 intravascularly. The needle-shielding feature and luer access port aid in the prevention of needlestick injuries. Blood is contained within the device during the catheter insertion process aiding in the prevention of blood exposure. This catheter may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness of procedure.

The 18-24 gauge Nexiva catheters are suitable for use with power injectors rated for a maximum of 300 psi when the luer access port(s) is removed and a direct connection is made.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: __X__ OR Over-The-Counter Use: _____

William M. Burdick

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

510(k) Number: K032843