Becton Dickinson Infusion Therapy Systems Inc.
Sandy UT 84070

**BD Intima II™ IV Catheter**
**510(k) Summary**

**Submitter:** Becton Dickinson Infusion Therapy Systems Inc.
9450 South State Street
Sandy, UT 84070

JUN - 3 2010

**Contact person:** Jane Stickel, Director, Regulatory Affairs

**Telephone number:** (801) 565-2686

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**Date summary prepared:** April 9, 2010

**Trade name:** BD Intima II™ IV Catheter

**Common name:** Peripheral Intravascular Catheter or IV Catheter

**Classification name:** Intravascular Catheter 21 CFR § 880.5200

**Panel and product code:** 80FOZ

**Predicate devices:** BD Intima™ Catheter System K833657
BD Insyte-N ™ IV Catheter K843033

**Product description:**

The Intima II IV Catheter consists of a Vialon® material catheter, a notched needle to enhance flashback visualization, septum, extension tubing and either a straight or Y Luer connector. A needle-accessed PRN is attached to the Luer connector. An end cap is attached to the second Luer connector on the Y design. Blood is contained within the device. A slide clamp is provided on the extension tube. A notched needle resides within the catheter until it is withdrawn through the septum after the catheter has been threaded into the vein. The needle unit includes a paddle that is held during the insertion process. This device does not include a needle-shielding mechanism.

| Catalog Number | Product Description |
|---|---|
| 383400 | 18G x 1.16" (1.3mm x 30mm) Straight luer connection site |
| 383401 | 20G x 1.16" (1.1mm x 30mm) Straight luer connection site |
| 383402 | 22G x 1.00" (0.9mm x 25mm) Straight luer connection site |
| 383403 | 24G x 0.75" (0.7mm x 19mm) Straight luer connection site |
| 383404 | 22G x 0.75" (0.9mm x 19mm) Straight luer connection site |
| 383405 | 18G x 1.16" (1.3mm x 30mm) Y luer connection site |
| 383406 | 20G x 1.16" (1.1mm x 30mm) Y luer connection site |
| 383407 | 22G x 1.00" (0.9mm x 25mm) Y luer connection site |
| 383408 | 24G x 0.75" (0.7mm x 19mm) Y luer connection site |
| 383409 | 22G x 0.75" (0.9mm x 19mm) Y luer connection site |

**Indications for Use:**

Becton Dickinson Infusion Therapy Systems Inc.
Sandy UT 84070

The BD Intima II™ IV Catheter is inserted into a patient's vascular system for short-term use to monitor blood pressure or administer fluids intravascularly.

**Nonclinical test results and technological characteristic comparisons submitted to determine substantial equivalence:**

The following technological characteristics of the BD Intima II IV Catheter are substantially equivalent per gauge size to the two predicate devices, the BD Insyte IV Catheter and BD Intima Catheter System:

- Intended use
- Distal end configuration
- Minimum catheter/adapter bond strength
- Vialon™ material catheter
- No needle-shielding mechanism
- Biocompatibility ISO 10993
- Gauge sizes color coded according to ISO 10555-5
- Maximum cannula penetration force
- Maximum catheter tip penetration
- Maximum catheter drag
- EtO sterilization

Due to product design and/or customer requirements, the following technological characteristics of the BD Intima II IV Catheter differ from the two predicate devices:

- Effective catheter lengths and gauge sizes
- Integrated PVC extension tubing with PRN
- Nominal water flow rate
- Flexible wings on catheter adapter
- Notched needle
- Flexible wings on catheter adapter
- Minimum cannula/cannula hub bond strength
- Catheter lie distance
- Component materials

In determining substantial equivalence between the subject and predicate devices, testing was done per in-house protocol and according with the following standards, when applicable:

- ISO 10555-1:1995/AMD2:2004 Sterile, single-use intravascular catheters - Part 1 General Requirements: *Testing conformed with all sections of this standard.*
- ISO 10555-5 Amd 1:1999, Corr 1:2002 Sterile, single-use intravascular catheters – Part 5: *Testing conformed to all sections of this standard with the exception of Sections 4.3 and 4.4.4. Section 4.3 relates to the identification*

*of lumens on a multilumen catheter and does not apply to the Intima II device since it is a single lumen catheter. Section 4.4.4 states that a vent fitting shall be provided. This requirement does not apply to the Intima II device since it is vented via a notch in the needle cannula, not a vent fitting.*

- ISO 594/2:1998 Conical fittings with 6% (Luer) taper for syringes, needles, and certain other medical equipment – Part 2 Lock fittings: *Testing conformed with all sections of this standard.*

The initial biocompatibility testing of the Intima II device conformed to ISO 10993 Part 1:1992 and revisions (1997), and FDA Blue Book Memorandum #G95-1 pertaining to the selection of tests and overall assessment. Various sub-parts of the ISO 10993 standard are updated on independent cycles. To address these changes to the ISO standards, all internal protocols and methods are reviewed and updated as necessary to ensure continued compliance with the standard. Additional testing is performed in the case of significant changes to the standard which may have the potential to impact the test results. In the case of the Intima II device, all ISO 10993 sub-parts which were re-issued in 2009 (e.g. 10993 Part 1, Part 3, and Part 5) have been addressed and the product remains in compliance with these requirements.

| Test | Test Method | Results |
|---|---|---|
| Cytotoxicity | ISO 10993-5 | Passed |
| Sensitization | ISO 10993-10 | Passed |
| Irritation or Intracutaneous Reactivity - | ISO 10993- 10 | Passed |
| Acute Systemic Toxicity | ISO 10993-11 | Passed |
| Subacute or Subchronic Toxicity | ISO 10993-11 | Passed |
| Genotoxicity | ISO 10993-3 | Passed |
| Implantation | ISO 10993-6 | Passed |
| Hemocompatibility | ISO 10993-4 | Passed |

The stability test report included in the 510(k) submission supports a shelf life of 3 years.

**Clinical tests submitted:**

No clinical test results were included in this submission.

**Conclusions drawn from nonclinical tests to demonstrate that the device is safe and effective as the legally marketed devices:**

Performance testing was conducted in accordance with consensus standards and design control requirements. Nonclinical test results and technological characteristics of like gauge size catheters were shown to be equivalent between the subject device and the two predicate devices. The differences among devices do not raise any new issues of safety or effectiveness. Refer to the two previous tables for the testing conducted to determine substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Becton Dickinson Infusion Therapy Systems Incorporated
C/O Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, Minnesota 55313

JUN – 3 2010

Re: K100775
Trade/Device Name: BD Intima II™ Closed IV Catheter
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: FOZ
Dated: May 21, 2010
Received: May 24, 2010

Dear Mr. Job:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Susan Runner

Anthony D. Watson, B.S., M.S., M.B.A.
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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Becton Dickinson Infusion Therapy Systems Inc.
Sandy, UT 84070

# INDICATIONS FOR USE

***Device Name:*** Intima II™ IV Catheter

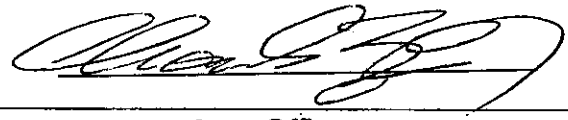
***Indications for Use:***

The BD Intima II IV Catheter is inserted into a patient's vascular system for short-term use to monitor blood pressure or administer fluids intravascularly.

Prescription Use: __X__ AND/OR Over-the-Counter Use: _____

(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 K100775