DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

April 9, 2015

Becton Dickinson Infusion Therapy Systems Inc.
Mr. John Roberts
Manager, Regulatory Affairs
9450 South State Street
Sandy, UT 84070

Re: K143610
Trade/Device Name: BD Intima II™ Closed IV Catheter System
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: FOZ
Dated: March 12, 2015
Received: March 13, 2015

Dear Mr. Roberts:

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 contact 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. 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 Erin I. Keith, M.S.
Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143610

K143610

Device Name
BD Intima II Closed IV Catheter System

Indications for Use *(Describe)*

The BD Intima II Closed IV Catheter System is inserted into a patient's vascular system for short-term use to monitor blood pressure or administer fluids intravascularly. These devices may be used for any patient population with consideration given to adequacy of vascular anatomy, procedure being performed, fluids being infused, and duration of therapy.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K143610

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Helping all people live healthy lives

510(k) Summary

21 CFR §807.92

BD Intima II™ Closed IV Catheter System

Submitter Information	Submitter Name: Submitter Address:	Becton Dickinson Infusion Therapy Systems Inc. 9450 South State Street Sandy, UT 84070
	Contact Person:	John Roberts Regulatory Affairs Manager Phone: 801.565.2673 Fax: 801.304.3963 Email: john_w_roberts@bd.com
	Date of Preparation:	9 April 2015
Subject Devices	Trade Name: Common Name: Classification Name: CFR Reference: Classification Panel:	BD Intima II™ Closed IV Catheter System Peripheral Intravascular or IV Catheter FOZ - Intravascular Catheter 21 CFR 880.5200 - Class II General Hospital
Predicate Devices	Trade Name: 510(k) Reference: Common Name: Classification Name: CFR Reference: Classification Panel:	BD Intima II™ Closed IV Catheter System K100775 Peripheral Intravascular or IV Catheter FOZ - Intravascular Catheter 21 CFR 880.5200 - Class II General Hospital
Device Description	The BD Intima II™ Closed IV Catheter System is a closed system IV Catheter. The closed system is designed to keep blood contained within the device throughout the insertion process. The system consists of a radiopaque Vialon™ material catheter, a notched needle for flashback visualization, a septum to remove visible blood from the needle tubing, a clamp (slide clamp/pinch clamp), extension tubing and Luer connector. It incorporates an integrated extension set which is available in two configurations: Y Connection (dual port) and Straight Connection (single port). The Luer connector is color-coded to indicate catheter gauge. It is provided EO sterilized to achieve a Sterility Assurance Level (SAL) of 10^{-6}. The package system is able to maintain the sterility during its specified shelf life of 3 years.	

Indications for Use	The BD Intima II Closed IV Catheter System is inserted into a patient's vascular system for short-term use to monitor blood pressure or administer fluids intravascularly. These devices may be used for any patient population with consideration given to adequacy of vascular anatomy, procedure being performed, fluids being infused, and duration of therapy.

Technological Characteristics

Technological characteristics of the subject device are equivalent to the predicate. The BD Intima IITM Closed IV Cather System achieves its intended use based on the same technology and principles of operation. The subject device has been modified from the predicate as listed below. The results of design verification demonstrate that these changes are substantially equivalent to the predicate device. All other aspects of the subject device are identical to those of the predicate device.

- Change to various adhesives and lubricants utilized during assembly
- Qualification of new pinch clamp as alternate to the current slide clamp;

Attribute	SUBJECT DEVICE	PREDICATE DEVICE
Indications for Use	BD Intima II™ Closed IV Catheter System is inserted into a patient's vascular system for short-term use to monitor blood pressure or administer fluids intravascularly.	BD Intima II™ Closed IV Catheter System is inserted into a patient's vascular system for short-term use to monitor blood pressure or administer fluids intravascularly.
Design	A single-winged, polyurethane IV Catheter with an integrated extension set incorporating either a single port or Y (dual)-port injection site. Incorporates BD Instaflash technology to assist with flashback visualization	A single-winged, polyurethane IV Catheter with an integrated extension set incorporating either a single port or Y (dual)-port injection site. Incorporates BD Instaflash technology to assist with flashback visualization

	Component	Subject Device	Predicate Device
Materials	Catheter Tubing	BD Vialon	BD Vialon
	Catheter Tipping Lubricant	Silicone	Silicone
	Catheter Lubricant	Silicone	Silicone
	Metal Wedge	Stainless Steel	Stainless Steel
	Y-Adapter	Propionate	Propionate
	Septum/Sleeve Stopper	Polyisoprene	Polyisoprene
	Needle	Stainless Steel	Stainless Steel
	Needle Cover	Polyethylene	Polyethylene
	Extension Tubing	Polyvinyl Chloride	Polyvinyl Chloride
	Pinch Clamp	Polyoxymethylene	Not applicable
	Slide Clamp	Polystyrene	Polystyrene
	Luer Connection Site	Polypropylene	Polypropylene
	PRN Body	Polycarbonate	Polycarbonate

	PRN Injection Port	Polyisoprene	Polyisoprene
	PRN Shrink Wrap Band	Polyvinyl Chloride	Polyvinyl Chloride
	Cap	Acrylonitrile Butadiene Styrene	Acrylonitrile Butadiene Styrene
	Extension Tubing Adhesive	UV-Cured Epoxy	UV-Cured Epoxy
	Needle Adhesive	UV-Cured Epoxy	2-Part Epoxy
	Septum Adhesive	UV-Cured Epoxy	UV-Cured Epoxy
	Paddle Hub	Polystyrene	Polystyrene
Physical / Mechanical Specifications	**SUBJECT DEVICE**		**PREDICATE DEVICE**
	Catheter Diameters: 18G, 20G, 22G, 24G Catheter Lengths: 0.75", 1.00", 1.16"		Catheter Diameters: 18G, 20G, 22G, 24G Catheter Lengths: 0.75", 1.00", 1.16"

Summary of Performance Tests

Pursuant to 21 CFR 820.30, Design Controls, design verification tests were performed based on the risk analysis, and the results of these tests demonstrate that the BD Intima II™ Closed IV Catheter System is substantially equivalent manner to the predicate device. Design Verification testing included the following:

Characteristic / Test Performed	Test Method	Results
Biocompatibility	Per ISO 10993	Pass
Needle/Paddle Hub Pull Force	Same Methodology as Predicate	Pass
Catheter/Catheter Adaptor Pull Force	Same Methodology as Predicate	Pass
Extension Tubing/Catheter Adapter Pull Force	Same Methodology as Predicate	Pass
Septum Burst Test	Same Methodology as Predicate	Pass
Catheter Burst Test	Same Methodology as Predicate	Pass

Summary of Substantial Equivalence

Based on the indications for use, technological characteristics, and safety and performance testing, the subject BD Intima II™ Closed IV Catheter meets all predetermined requirements in accordance with 21 CFR 820.30, Design Controls, and demonstrates that the subject device is substantially equivalent to the predicate devices.