DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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August 17, 2017

Becton, Dickinson and Company
% Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, Minnesota 55313

Re: K172204
Trade/Device Name: BD Intima II PLUS Closed IV Catheter System
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular catheter
Regulatory Class: Class II
Product Code: FOZ
Dated: July 19, 2017
Received: July 21, 2017

Dear Mark 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 contact the Division of Industry and Consumer Education (DICE) 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" (21 CFR 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 Industry and Consumer Education (DICE) 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,

Tara A. Ryan -S

for
Lori Wiggins
Acting 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)*

Device Name
BD Intima II PLUS Closed IV Catheter System

Indications for Use *(Describe)*
The BD Intima II PLUS 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Helping all people live healthy lives

K172204 **510(k) Summary**

21 CFR §807.92

BD Intima II PLUS™ 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:	Henry Boland Staff Regulatory Affairs Specialist henry.boland@bd.com (801) 565-2550 (phone)
	Date of Preparation:	June 30, 2017
Subject Device	Trade Name: Common Name: Regulation Number: Regulation Name: Regulatory Class: Product Code: Classification Panel:	BD Intima II PLUS™ Closed IV Catheter System Peripheral Intravascular or IV Catheter 21 CFR §880.5200 Intravascular Catheter II FOZ General Hospital
Predicate Device	Trade Name: 510(k) Reference: Common Name: Regulation Number: Regulation Name: Regulatory Class: Product Code: Classification Panel:	BD Intima II™ Closed IV Catheter System K143610 Peripheral Intravascular or IV Catheter 21 CFR §880.5200 Intravascular Catheter II FOZ General Hospital
Reason for Submission	The reason for his submission is to notify CDRH of modifications to the BD Intima II™ Closed IV Catheter System, including: 1) a change to extension tubing and PRN shrink wrap band from PVC to non-PVC materials; 2) the removal of the slide clamp option (only a pinch clamp option will be available); 3) the addition of new Y connection (dual port) with dual PRN adapter configurations; 4) the addition 0.56” length catheter configurations.	
Device Description	The BD Intima II PLUS™ Closed IV Catheter System is a closed system IV catheter 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 pinch clamp, extension tubing and Luer connector. The system incorporates an integrated extension set which is available in three configurations: 1) Y Connection (dual port) with PRN adapter and end cap; 2) Y Connection (dual port) with two PRN adapters; and 3) Straight Connection (single port) with PRN adapter. The Luer connector is color-coded to indicate catheter gauge size. The system is provided EO sterilized to achieve a Sterility Assurance Level (SAL) of 10^{-6}. The package system is able to maintain	

product sterility during its specified shelf life of 3 years.

Indications for Use

(21 CFR §807.92(a)(5))

The subject device Indications for Use is the same as the predicate BD Intima II Closed IV Catheter System (K143610), with the exception of the device trade name. As such, the differences between the subject and predicate device Indications for Use do not change the intended use of the predicate devices or raise different questions of safety and effectiveness.

SUBJECT DEVICE	PREDICATE DEVICE (K143610)
The BD Intima II **PLUS**™ 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.	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 substantially equivalent to the predicate device. The subject BD Intima II PLUS™ Closed IV Cather System achieves its intended use based on the same technology and principles of operation as the predicate BD Intima II™ Closed IV Cather System. The subject device has been modified from the predicate device 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 Extension Tubing and PRN Shrink Wrap Band materials from PVC to non-PVC materials
- Removal of slide clamp component *(only pinch clamp provided)*
- Qualification of new product configurations:
  - Y Connection (dual port) with two pre-attached PRN adapters
  - 0.56” length catheter configuration

Attribute	SUBJECT DEVICE	PREDICATE DEVICE (K143610)
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	Same as predicate	BD Vialon™ Polyurethane
	Catheter Tipping Lubricant	Same as predicate	Silicone
	Catheter Lubricant	Same as predicate	Silicone
	Metal Wedge	Same as predicate	Stainless Steel
	Y-Adapter	Same as predicate	Propionate
	Septum/Sleeve Stopper	Same as predicate	Polyisoprene
	Needle	Same as predicate	Stainless Steel

	Needle Cover	Same as predicate	Polyethylene
	Extension Tubing	**Thermoplastic Polyurethane**	Polyvinyl Chloride
	Pinch Clamp	Same as predicate	Polyoxymethylene
	Slide Clamp	***No slide clamp option***	Polystyrene
	Luer Connection Site	Same as predicate	Polypropylene
	PRN Body	Same as predicate	Polycarbonate
	PRN Injection Port	Same as predicate	Polyisoprene
	PRN Shrink Wrap Band	**Polyethylene Terephthalate**	Polyvinyl Chloride
	Cap	Same as predicate	Acrylonitrile Butadiene Styrene
	Extension Tubing Adhesive	Same as predicate	UV-Cured Epoxy
	Needle Adhesive	Same as predicate	UV-Cured Epoxy
	Septum Adhesive	Same as predicate	UV-Cured Epoxy
	Paddle Hub	Same as predicate	Polystyrene

	SUBJECT DEVICE		PREDICATE DEVICE	
Physical / Mechanical Specifications	Catheter Diameters	Catheter Lengths	Catheter Diameters	Catheter Lengths
	18G, 20G, 22G, 24G	**0.56”**, 0.75”, 1.00”, 1.16”	18G, 20G, 22G, 24G	0.75”, 1.00”, 1.16”
Product Configurations	• Y Connection (dual port) with PRN adapter and end cap • **Y Connection (dual port) with two PRN adapters** • Straight Connection (single port) with PRN adapter		• Y Connection (dual port) with PRN adapter and end cap • Straight Connection (single port) with PRN adapter	

Summary of Performance Tests

Performance tests completed on the subject device were limited to those tests required to support a determination of substantial equivalence to the predicate devices. A risk analysis was conducted to assess the impact of the proposed modifications to the subject devices. When technological characteristics between the subject and predicate devices were found to be identical, results of performance testing conducted on the predicate devices were applied to the subject device. The performance tests listed below were identified to ensure that specified design requirements were met:

- Extension Tubing / Catheter Adapter Pull Force
- Extension Tubing / Catheter Adapter Joint Leakage Pressure
- Extension Tubing Pull Out Force
- Clamp Seal Pressure
- Package Integrity

In addition, the following biocompatibility testing was conducted in accordance with *ISO 10993-1:2009, Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing Within a Risk Management Process*.

- Cytotoxicity
- Sensitization
- Intracutaneous Reactivity
- Systemic Toxicity (Acute)
- Haemocompatibility

	• Pyrogenicity (Material-Mediated Rabbit Pyrogen) Finally, particulate analysis of the surface and fluid path was conducted. Per the design control requirements specified in 21 CFR §820.30, the subject device met all predetermined acceptance criteria for the above-listed performance tests, demonstrating substantial equivalence to the predicate devices.
Summary of Substantial Equivalence	Based on the indications for use, technological characteristics, and performance testing, the subject BD Intima II PLUS™ Closed IV Catheter meets all pre-determined requirements in accordance with 21 CFR §820.30, Design Controls, and demonstrates that the subject device is substantially equivalent to the predicate BD Intima II™ Closed IV Catheter System.