June 2, 2021

Becton, Dickinson and Company
Kimberly Geisler
Sr. Manager, Regulatory Affairs
9450 South State Street
Sandy, Utah 84070

Re: K200891
Trade/Device Name: BD Intima II™ Closed IV Catheter System, 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, FPA
Dated: April 30, 2021
Received: May 3, 2021

Dear Kimberly Geisler:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Payal Patel
Acting Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K200891

Device Name
BD Intima II™ Closed IV Catheter System and
BD Intima II PLUSTM 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.

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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510(k) Summary (21 CFR §807.92) - K200891

BD Intima II™ Closed IV Catheter System and

BD Intima II PLUS™ Closed IV Catheter System

Submitter Information	Submitter Name:	Becton Dickinson Infusion Therapy Systems Inc.
	Submitter Address:	9450 South State Street Sandy, Utah 84070
	Contact Person:	Kimberly Geisler Sr. Manager, Regulatory Affairs kimberly.geisler@bd.com (801) 565-2422 (phone)
	Date of Preparation:	June 2, 2021
Subject Device	Trade Name:	BD Intima II™ Closed IV Catheter System BD Intima II PLUS™ Closed IV Catheter System
	Common Name:	Peripheral Intravascular or IV Catheter
	Regulation Number:	21 CFR §880.5200
	Regulation Name:	Intravascular Catheter
	Regulatory Class:	II
	Product Code:	FOZ (primary); FPA (secondary)
	Classification Panel:	General Hospital
Predicate Device 1	Trade Name:	BD Intima II™ Closed IV Catheter System
	510(k) Reference:	K143610, cleared 09 April 2015
	Common Name:	Peripheral Intravascular or IV Catheter
	Regulation Number:	21 CFR §880.5200
	Regulation Name:	Intravascular Catheter
	Regulatory Class:	II
	Product Code:	FOZ
	Classification Panel:	General Hospital
Predicate Device 2	Trade Name:	BD Intima II PLUS™ Closed IV Catheter System
	510(k) Reference:	K172204, cleared 17 August 2017
	Common Name:	Peripheral Intravascular or IV Catheter
	Regulation Number:	21 CFR §880.5200
	Regulation Name:	Intravascular Catheter
	Regulatory Class:	II
	Product Code:	FOZ
	Classification Panel:	General Hospital

Predicate Device 3	Trade Name:	MaxZero™ Needleless Connector (MZ1000)
	510(k) Reference:	K132413, cleared 29 August 2013
	Common Name:	Intravascular Administration Set or Needleless Connector
	Regulation Number:	21 CFR §880.5440
	Regulation Name:	Intravascular Administration Set
	Regulatory Class:	II
	Product Code:	FPA
	Classification Panel:	General Hospital
Reason for Submission	The reason for this submission is to expand the product offerings within the BD Intima II™ and Intima II PLUS™ Closed IV Catheter System product lines, add a performance specification for the BD Intima II PLUS™ Closed IV Catheter System single port 20G – 24G configurations to withstand pressure up to 300psi, submit modifications to various system components, and modify the sterilization method for the MaxZero™ Needleless Connector.	
Device Description	The BD Intima II™ and Intima II PLUS™ Closed IV Catheter Systems are closed system IV catheters 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 (4.0 IN), and a Luer connector. The 24G and 26G products are also provided with 2.8 IN extension tubing. The system incorporates an integrated extension set which is available in multiple configurations: 1) Y connection (dual port) with a PRN adapter or needleless connector (MaxZero) and end cap; 2) Y connection (dual port) with two PRN adapters or two needleless connectors (MaxZero); 3) Y connection (dual port) with one PRN adapter and one needleless connector (MaxZero); and 4) Straight connection (single port) with a PRN adapter or needleless connector (MaxZero). The Luer connectors are color-coded to indicate catheter gauge size.	
Indications for Use (21 CFR §807.92(a)(5))	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. 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.	

Technological Characteristics	The BD Intima™ II and Intima II PLUS™ Closed IV Catheter Systems achieve their intended uses based on the same technology and principles of operation as the predicate BD Intima II™ and Intima II PLUS™ Closed IV Catheter Systems, as well as the MaxZero™ Needleless Connector. The subject devices have been modified from the predicate devices as listed below. The changes to device design did not alter final product performance specifications and the results of design verification demonstrate that the subject devices are substantially equivalent to the predicate devices. All other aspects of the subject device are identical to those of the predicate devices. Tables comparing the subject and predicate devices are provided below.
	• Qualification of new product configurations:
	  ○ Y connection (dual port) with MaxZero™ Needleless Connector and end cap;
	  ○ Y connection (dual port) with dual MaxZero™ Needleless Connectors;
	  ○ Y connection (dual port) with PRN adapter and MaxZero™ Needleless Connector;
	  ○ Straight Connection (single port) with MaxZero™ Needleless Connector;
	  ○ 26G needle configuration (with 2.8 IN and 4.0 IN extension tubing); and
	  ○ 2.8 IN extension tubing for 24G products.
	• Addition of a performance specification for the BD Intima II PLUS™ Closed IV Catheter System single port 20G – 24G configurations to withstand pressure up to 300psi.
	• Design modifications to various components of the BD Intima II™ and Intima II PLUS™ Closed IV Catheter Systems including:
	  ○ modification of the paddle hub dimensions and reduction of colorant concentration;
	  ○ reduction of luer connector colorant concentration;
	  ○ modification to cannula profile and dimensions;
	  ○ modification to 18G Y luer connector dimensions;
	  ○ update to luer component torque off specification;
	  ○ qualification of new packaging bottom web material; and
	  ○ introduction of slim pinch clamp.
	• Modification to catheter tipping lubricant and catheter lubricant to remove HCFC solvent and modification to catheter lubricant application process.
	• Change in sterilization method for MaxZero™ Needleless Connector.

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Attribute	SUBJECT DEVICE BD Intima™ II Closed IV Catheter System and BD Intima II PLUS™ Closed IV Catheter System	PREDICATE DEVICE 1 BD Intima II™ Closed IV Catheter System (K143610)	PREDICATE DEVICE 2 BD Intima II PLUS™ Closed IV Catheter System (K172204)
Fundamental Scientific Technology	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.	
Catheter Tubing	BD Vialon™ Polyurethane	BD Vialon™ Polyurethane	
Catheter Tipping Lubricant	Silicone Fluid (no change to material, “fluid” added for clarity)	Silicone	
Catheter Lubricant	Silicone Fluid (no change to material, “fluid” added for clarity)	Silicone	
Metal Wedge	Stainless Steel	Stainless Steel	
Y-Adapter (Catheter Adapter)	Propionate	Propionate	
Septum/Sleeve Stopper	Polyisoprene	Polyisoprene	
Needle (Cannula)	Stainless Steel	Stainless Steel	
Needle (Cannula) Lubricant	Silicone Fluid	Not specified	
Needle Cover	Polyethylene	Polyethylene	
Extension Tubing	Polyvinyl Chloride (Intima II only)	Polyvinyl Chloride	N/A
	Thermoplastic Polyurethane (Intima II PLUS only)	N/A	Thermoplastic Polyurethane
Pinch Clamp Material	Polyoxymethylene (POM)	Polyoxymethylene	
Pinch Clamp Design	Standard **and Slim**	Standard	
Slide Clamp	Polystyrene (Intima II only)	Polystyrene	N/A
Luer Connection Site	Polypropylene with gauge-specific colorant	Polypropylene (colorant not specified)	
PRN Adapter Body	Polycarbonate	Polycarbonate	
PRN Adapter Injection Port	Polyisoprene	Polyisoprene	
PRN Adapter Shrink Wrap Band	Polyvinyl Chloride (Intima II only)	Polyvinyl Chloride	N/A
	Polyethylene Terephthalate (Intima II PLUS only)	N/A	Polyethylene Terephthalate
End Cap	Acrylonitrile Butadiene Styrene	Acrylonitrile Butadiene Styrene	
Extension Tubing Adhesive	Epoxy	UV-Cured Epoxy	

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Attribute	SUBJECT DEVICE BD Intima™ II Closed IV Catheter System and BD Intima II PLUS™ Closed IV Catheter System	PREDICATE DEVICE 1 BD Intima II™ Closed IV Catheter System (K143610)	PREDICATE DEVICE 2 BD Intima II PLUS™ Closed IV Catheter System (K172204)
(Extension Tubing/Catheter Adapter Adhesive)	(no change to material, general term used for adhesive)		
Needle Adhesive (Cannula Bonding Adhesive)	Epoxy (no change to material, general term used for adhesive)	UV-Cured Epoxy	
Septum Adhesive	Epoxy (no change to material, general term used for adhesive)	UV-Cured Epoxy	
Paddle Hub	Polystyrene and White Colorant	Polystyrene (colorant not specified)	
Physical / Mechanical Specifications	Catheter Diameters 18G, 20G, 22G, 24G, **26G** Catheter Lengths 0.56 IN (Intima II PLUS only), 0.75 IN, 1.00 IN, 1.16 IN	Catheter Diameters 18G, 20G, 22G, 24G Catheter Lengths 0.75IN, 1.00IN, 1.16IN	Catheter Diameters 18G, 20G, 22G, 24G Catheter Lengths 0.56IN, 0.75IN, 1.00IN, 1.16IN
Product Configurations	• Y connection (dual port) with PRN adapter and end cap • Y connection (dual port) with two PRN adapters • **Y connection (dual port) with MaxZero™ Needleless Connector and end cap** • **Y connection (dual port) with MaxZero™ Needleless Connector and PRN adapter** • **Y connection (dual port) with two MaxZero™ Needleless Connectors** • Straight connection (single port) with PRN adapter • **Straight connection (single port) with MaxZero™ Needleless Connector**	• Y Connection (dual port) with PRN and end cap • Straight Connection (single port) with PRN adapter	• 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

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Attribute	SUBJECT DEVICE BD Intima™ II Closed IV Catheter System and BD Intima II PLUS™ Closed IV Catheter System	PREDICATE DEVICE 1 BD Intima II™ Closed IV Catheter System (K143610)	PREDICATE DEVICE 2 BD Intima II PLUS™ Closed IV Catheter System (K172204)
Extension Tubing Length	**2.8 IN (24G and 26G only)** 4.0 IN	4.0 IN	
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide

Attribute	SUBJECT DEVICE	PREDICATE DEVICE 3 MaxZero™ Needleless Connector (K132413)
MaxZero Housing Top	Polycarbonate	Polycarbonate
MaxZero Housing Bottom	Polycarbonate	Polycarbonate
MaxZero Valve	Silicone Rubber and Blue Colorant	Silicone Rubber and Blue Colorant
MaxZero Valve Lubricant	Silicone Fluid	Silicone Fluid
Sterilization Method	**Ethylene Oxide**	E-beam

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Summary of Safety and Performance Tests	Performance tests completed on the subject devices 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 devices. The performance tests listed below were conducted to ensure that the subject devices meet pre-determined design requirements:
	• Needleless Connector Removal Torque (BD internal)
	• Needleless Connector Leakage Pressure (BD internal)
	• Needleless Connector Microbial Ingress
	• Needleless Connector EtO Sterilization Compatibility
	  ◦ Flow rate (BD internal)
	  ◦ Back pressure (BD internal)
	  ◦ Insertion force (BD internal)
	  ◦ Droplet size (BD internal)
	  ◦ Droplet separation (BD internal)
	  ◦ Activations (BD internal)
	  ◦ Shelf-Life (BD internal)
	• Qualification of 26G catheters
	  ◦ Lie distance (ISO 10555-1, §4.4.2)
	  ◦ Needle tip sharpness (ISO 10555-5, §4.3.3.2)
	  ◦ Joint strength (ISO 10555-5, §4.3.3.4)
	  ◦ Flow rate (ISO 10555-1, §4.9)
	• Verification of the BD Intima II PLUS™ Closed IV Catheter System single port 20G – 24G configurations to withstand pressure up to 300psi
	  ◦ Flow rate (ISO 10555-1, §4.9)
	  ◦ Burst and leaking testing (ISO 10555-1, §4.10)
	• Particulate Matter testing per USP <788>
	• Microbial Ingress testing
	• Evaluation of MR Compatibility per ASTM F2182-19
	
	In addition, a biocompatibility evaluation was conducted in accordance with *ISO 10993-1:2009, Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing Within a Risk Management Process* and the FDA's guidance Use of International Standard ISO 10993-1, "*Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*" (issued June 16, 2016). Biocompatibility data submitted in support of the predicate devices was

	leveraged and the following biocompatibility studies were conducted to support the design changes within the scope of this submission: • Cytotoxicity • Sensitization • Intracutaneous Reactivity • Acute Systemic Toxicity • Pyrogenicity (Material-Mediated Rabbit Pyrogen) • Subacute/Subchronic Toxicity • Haemocompatibility Per the design control requirements specified in 21 CFR §820.30, the subject devices 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 safety and performance testing, the subject BD Intima II™ and Intima II PLUS™ Closed IV Catheter Systems have been demonstrated to be substantially equivalent to the predicate devices.