March 20, 2019

Becton Dickinson Infusion Therapy Systems Inc.
% Mark Job
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, Minnesota 55313

Re: K183399
Trade/Device Name: BD Nexiva™ Closed IV Catheter System
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular catheter
Regulatory Class: Class II
Product Code: FOZ, FPA
Dated: March 11, 2019
Received: March 12, 2019

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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Geeta K.
Pamidimukkala -S

for Tina Kiang, Ph.D.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183399

Device Name

BD Nexiva Closed IV Catheter System

Indications for Use *(Describe)*

BD Nexiva closed IV catheter systems are intended to be inserted into a patient's peripheral vascular system for short term use to sample blood, monitor blood pressure, or administer fluids. 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 22-18 GA (0.9-1.3 mm) devices are suitable for use with power injectors set to a maximum pressure of 300 psi (2068 kPa) when access ports not suitable for use with power injectors are removed.

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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K183399

510(k) Summary (21 CFR §807.92)

BD Nexiva™ Closed IV Catheter System

Submitter Information	Submitter Name:	Becton Dickinson Infusion Therapy Systems Inc.
	Submitter Address:	9450 South State Street Sandy, UT 84070
	Contact Person:	Kimberly Geisler Regulatory Affairs Manager
	Email Address:	kimberly.geisler@bd.com
	Phone Number:	(801) 565-2422
	Fax Number	(801) 304-3963
	Date of Preparation:	March 14, 2019
Subject Device	Trade Name:	BD Nexiva™ Closed IV Catheter System
	Common Name:	Peripheral Intravascular or IV Catheter
	Regulation Number:	21 CFR §880.5200
	Regulation Name:	Catheter, intravascular, therapeutic, short-term less than 30 days
	Regulatory Class:	II
	Product Code:	FOZ (Primary); FPA (Secondary)
	Classification Panel:	General Hospital
Predicate Device 1	Trade Name:	BD Nexiva™ Closed IV Catheter System - Single Port with MaxZero™ Needleless Connector
	510(k) Reference:	K170336
	Common Name:	Peripheral Intravascular or IV Catheter
	Regulation Number:	21 CFR §880.5200
	Regulation Name:	Catheter, intravascular, therapeutic, short-term less than 30 days
	Regulatory Class:	II
	Product Code:	FOZ (primary); FPA (secondary)
	Classification Panel:	General Hospital
Predicate Device 2	Trade Name:	BD Nexiva™ Closed IV Catheter System
	510(k) Reference:	K161777
	Common Name:	Peripheral Intravascular or IV Catheter
	Regulation Number:	21 CFR §880.5200
	Regulation Name:	Catheter, intravascular, therapeutic, short-term less than 30 days
	Regulatory Class:	II
	Product Code:	FOZ
	Classification Panel:	General Hospital

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Reason for Submission	The reason for this submission is the addition of **BD Nexiva Closed IV Catheter System - Dual Port with MaxZero Needleless Connector** configurations to the BD Nexiva Closed IV Catheter System product offerings.
Device Description	BD Nexiva closed IV catheter systems are over-the-needle, intravascular catheters. These devices have a radiopaque BD Vialon catheter, needle, needle shield, septum, stabilization platform, integrated extension tubing, clamp, Luer adapter (single or dual port), vent plug, and pre-attached needleless connector (BD Q-Syte or MaxZero) (dual port configurations only). The needle and catheter are protected by a needle cover. A BD Q-Syte, MaxZero, or end cap with protective cover is provided in the unit package (not available with all configurations). The closed system is designed to keep blood contained within the device throughout the insertion process. The septum is designed to wipe visible blood from the needle surface as the needle is withdrawn from the catheter, further reducing the risk of blood exposure. The needle tip is passively protected when the needle is removed, reducing the risk of accidental needlestick injury. These devices have BD Instaflash needle technology, allowing for immediate visualization of blood along the catheter. Continuous blood return is seen in the extension tubing. The vent plug prevents blood leakage from the extension tubing during insertion. Both the stabilization platform and Luer connector are color coded to indicate catheter gauge size (24 GA (0.7 mm) = Yellow, 22 GA (0.9 mm) = Blue, 20 GA (1.1 mm) = Pink, 18 GA (1.3 mm) = Green).
Indications for Use **21 CFR §807.92(a)(5))**	The subject device Indications for Use is the same as the predicate devices, with two minor wording modifications: 1) addition of “peripheral” to clarify the location of placement within the patient’s vascular system; and 2) modification of “These catheters” to “These devices” for clarification and consistency. *BD Nexiva closed IV catheter systems are intended to be inserted into a patient’s **peripheral** vascular system for short term use to sample blood, monitor blood pressure, or administer fluids. 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 22-18 GA (0.9-1.3 mm) devices are suitable for use with power injectors set to a maximum pressure of 300 psi (2068 kPa) when access ports not suitable for use with power injectors are removed.*
Technological Characteristics	Technological characteristics of the subject and predicate devices are substantially equivalent with respect to the device design and materials. The subject BD Nexiva Closed IV Catheter System achieves its intended use based on the same technology and principles of operation as the predicate devices. Compared to the predicate devices, the subject device product offerings are being expanded to include the following **BD Nexiva Closed IV Catheter System – Dual Port with MaxZero Needleless Connector** configurations: • 24 GA x 0.56 IN – Dual Port with MaxZero • 24 GA x 0.75 IN – Dual Port with MaxZero • 22 GA x 1.00 IN – Dual Port with MaxZero • 22 GA x 1.75 IN – Dual Port with MaxZero • 20 GA x 1.00 IN – Dual Port with MaxZero • 20 GA x 1.25 IN – Dual Port with MaxZero • 20 GA x 1.75 IN – Dual Port with MaxZero • 18 GA x 1.25 IN – Dual Port with MaxZero

- 18 GA x 1.75 IN – Dual Port with MaxZero

Compared to the predicate devices, the subject **BD Nexiva Closed IV Catheter System – Dual Port with MaxZero Needleless Connector** configurations include a pre-attached MaxZero device on the Luer adapter and an additional MaxZero device in the unit package. Compared to the predicate devices, this represents a change to the connector on the Dual Port Y Luer adapter. No modifications are being made to the catheter sizes. Predicate and subject devices include the same catheter diameters (18 GA, 20 GA, 22 GA, 24GA) and catheter lengths (0.56 IN, 0.75 IN, 1.00 IN, 1.25 IN, 1.75 IN).

A comparison of the subject and predicate device technological characteristics is provided in the table below, with differences highlighted in **BOLD** text.

Attribute	SUBJECT BD Nexiva Closed IV Catheter System	PREDICATE 1 (K170336) BD Nexiva Closed IV Catheter System (Single Port) with MaxZero Needleless Connector	PREDICATE 2 (K161777) BD Nexiva Closed IV Catheter System
Indications for Use	BD Nexiva closed IV catheter systems are intended to be inserted into a patient's **peripheral** vascular system for short term use to sample blood, monitor blood pressure, or administer fluids. 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 22-18 GA (0.9-1.3 mm) devices are suitable for use with power injectors set to a maximum pressure of 300 psi (2068 kPa) when access ports not suitable for use with power injectors are removed.	BD Nexiva Closed IV Catheter System - Single Port with MaxZero Needleless Connector devices are intended to be inserted into a patient's vascular system for short term use to sample blood, monitor blood pressure, or administer fluids. These catheters 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 22-18 GA (0.9-1.3 mm) devices are suitable for use with power injectors set to a maximum pressure of 300 psi (2068 kPa) when access ports not suitable for use with power injectors are removed.	BD Nexiva closed IV catheter systems are intended to be inserted into a patient's vascular system for short term use to sample blood, monitor blood pressure, or administer fluids. These catheters 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 22-18 GA (0.9-1.3 mm) devices are suitable for use with power injectors set to a maximum pressure of 300 psi (2068 kPa) when access ports not suitable for use with power injectors are removed.
Classification	21 CFR §880.5200 Class II FOZ - Catheter, intravascular, therapeutic, short-term less than 30 days (primary) FPA - IV Administration Set (secondary)	21 CFR §880.5200 Class II FOZ - Catheter, intravascular, therapeutic, short-term less than 30 days (primary) FPA - IV Administration Set (secondary)	21 CFR §880.5200 Class II FOZ - Catheter, intravascular, therapeutic, short-term less than 30 days (primary)
510(k) Status	Subject of this premarket notification	K170336 – Clearance date March 10, 2017	K161777 – Clearance date August 29, 2016

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Fundamental Scientific Technology	Closed peripheral intravascular catheter system designed with an integrated extension set incorporating a single port or Y (dual)-port injection site. Incorporates BD Instaflash™ technology to assist with flashback visualization.	Closed peripheral intravascular catheter system designed with an integrated extension set incorporating a single port injection site. Incorporates BD Instaflash™ technology to assist with flashback visualization.	Closed peripheral intravascular catheter system designed with an integrated extension set incorporating a single port or Y (dual)-port injection site. Incorporates BD Instaflash™ technology to assist with flashback visualization.
Primary Device Components / Materials			
Needle	Stainless Steel	Stainless Steel	Stainless Steel
Catheter Tubing	Polyurethane + Barium Sulfate	Polyurethane + Barium Sulfate	Polyurethane + Barium Sulfate
Catheter Adapter Wings	TPE + Gauge-Specific Colorant	TPE + Gauge-Specific Colorant	TPE + Gauge-Specific Colorant
Catheter Adapter	Copolyester	Copolyester	Copolyester
Tip Shield	Polycarbonate + Grey Colorant	Polycarbonate + Grey Colorant	Polycarbonate + Grey Colorant
Grip / Needle Hub	Polycarbonate + White Colorant	Polycarbonate + White Colorant	Polycarbonate + White Colorant
Pinch Clamp	Acetal	Acetal	Acetal
Extension Tubing	Polyurethane	Polyurethane	Polyurethane
Luer Adapter	Copolyester	Copolyester	Copolyester
Q-Syte	Polycarbonate / Silicone	N/A	Polycarbonate / Silicone
MaxZero	Polycarbonate / Silicone	Polycarbonate / Silicone	N/A
Catheter Dimensions	Catheter Diameters 18 GA, 20 GA, 22 GA, 24GA Catheter Lengths 0.56 IN, 0.75 IN, 1.00 IN, 1.25 IN, 1.75 IN	Catheter Diameters 18 GA, 20 GA, 22 GA, 24GA Catheter Lengths 0.56 IN, 0.75 IN, 1.00 IN, 1.25 IN, 1.75 IN	Catheter Diameters 18 GA, 20 GA, 22 GA, 24GA Catheter Lengths 0.56 IN, 0.75 IN, 1.00 IN, 1.25 IN, 1.75 IN
Product Configurations	• Single Port	• Single Port	• Single Port
	• Single Port with MaxZero	• Single Port with MaxZero	N/A
	• Dual Port	N/A	• Dual Port
	• Dual Port with Q-Syte	N/A	• Dual Port with Q-Syte
	• Dual Port with Q-Syte and End Cap	N/A	• Dual Port with Q-Syte and End Cap
	• **Dual Port with MaxZero**	N/A	N/A
Sterility	Provided sterile (EO)	Provided sterile (EO)	Provided sterile (EO)

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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 predicate 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 conducted to ensure that the subject device meets specified design requirements:

- MaxZero Retention Rate (BD internal specification)
- MaxZero Removal Torque (BD internal specification)
- Flow Control Plug Retention Rate (BD internal specification)
- Packaging Integrity (ASTM F2096)
- Damage to Device (ISO 11607-1 §6.3.5) (testing conducted to ensure packaging system provides adequate protection to the product through the hazards of handling, distribution and storage)

Biocompatibility testing, conducted in accordance to 1) *ISO 10993-1:2009, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing* and 2) *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), was leveraged from the predicate devices, including:

- Cytotoxicity
- Sensitization
- Intracutaneous Reactivity
- Systemic Toxicity (Acute)
- Pyrogenicity (Material-Mediated Rabbit Pyrogen)
- Pyrogenicity (LAL)
- Subchronic Toxicity (subacute toxicity)
- Genotoxicity
- Implantation
- Haemocompatibility

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 results of performance testing, the subject BD Nexiva Closed IV Catheter System has been demonstrated to be substantially equivalent to the predicate devices.