September 22, 2023

Becton Dickinson Infusion Therapy Systems Inc.
Paul Holman
Regulatory Affairs Manager
9450 South State Street
Sandy, Utah 84070

Re: K231239
Trade/Device Name: Nexiva™ Closed IV Catheter System with NearPort™ IV Access
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: Class II
Product Code: FOZ, FPA
Dated: August 25, 2023
Received: August 25, 2023

Dear Paul Holman:

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,

Porsche Bennett

Porsche Bennett
For David Wolloscheck, Ph.D.
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)*
K231239

Device Name
Nexiva™ Closed IV Catheter System with NearPort™ IV Access

Indications for Use *(Describe)*
The Nexiva™ Closed IV Catheter System with NearPort™ IV Access is intended to be inserted into a patient's peripheral venous system for short term use to administer fluids and/or medications and to sample blood. 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 24-18 GA (0.7-1.3 mm) devices are suitable for use with power injectors set to a maximum pressure of 300 psi (2068 kPa) when connected to the NearPort™ IV Access.

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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K231239 510(k) Summary (21 CFR §807.92)

Nexiva™ Closed IV Catheter System with NearPort™ IV Access

Submitter Information	Submitter Name:	Becton Dickinson Infusion Therapy Systems Inc.
	Submitter Address:	9450 South State Street, Sandy, Utah 84070
	Contact Person:	Paul Holman, Regulatory Affairs Manager
	Email Address:	paul.holman@bd.com
	Phone Number:	(801) 522-5000
	Date of Preparation:	September 22, 2023
Subject Device	Trade Name:	Nexiva™ Closed IV Catheter System with NearPort™ IV Access
	Common Name:	Peripheral Intravascular or IV Catheter
	510(k) Reference:	K231239
	Regulation Number:	21 CFR §880.5200
	Regulation Name:	Catheter, intravascular, therapeutic, short-term less than 30 days
	Regulatory Class:	II
	Product Code:	FOZ, FPA
	Classification Panel:	General Hospital
Predicate Device	Trade Name:	BD Nexiva™ Closed IV Catheter System
	Common Name:	Peripheral Intravascular or IV Catheter
	510(k) Reference:	K183399
	Regulation Number:	21 CFR §880.5200
	Regulation Name:	Catheter, intravascular, therapeutic, short-term less than 30 days
	Regulatory Class:	II
	Product Code:	FOZ, FPA
	Classification Panel:	General Hospital
Reason for Submission	The purpose of this submission is to notify the FDA of the introduction of the Nexiva™ Closed IV Catheter System with NearPort™ IV Access, allowing for compatibility with a needle-free blood draw device (e.g., PIVO™ Pro Needle-free Blood Collection Device).	
Device Description	The Nexiva™ Closed IV Catheter System with NearPort™ IV Access is an over-the-needle, intravenous (IV) catheter. These devices have a radiopaque Vialon™ catheter tubing, needle, needle shield, septum, stabilization platform, long extension tubing, clamp, Luer adapter, and vent plug. The needle and catheter tubing are protected by a needle cover. A MaxZero™ needle-free connector with protective cover is provided in the package.	

	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 Instaflash™ Needle Technology, allowing for immediate visualization of blood return along the catheter. Continuous blood return is seen in the long extension tubing. The vent plug and the NearPort™ IV Access prevent blood leakage from the long extension tubing during insertion. Both the long extension tubing and NearPort™ IV Access are suitable to administer fluids and/or medications and to sample blood. In addition, the NearPort™ IV Access is compatible with the PIVO™ Pro Needle-free Blood Collection Device for needle-free blood draws and is suitable for use with power injectors set to a maximum pressure of 300 psi (2068 kPa). These devices are available with wings. The catheter hub and wings are color coded to indicate the 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 Nexiva™ Closed IV Catheter System with NearPort™ IV Access is intended to be inserted into a patient's peripheral venous system for short term use to administer fluids and/or medications and to sample blood. 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 24-18 GA (0.7-1.3 mm) devices are suitable for use with power injectors set to a maximum pressure of 300 psi (2068 kPa) when connected to the NearPort™ IV Access.
Technological Characteristics	Technological characteristics of the subject device are substantially equivalent to the predicate device. The subject device, Nexiva™ Closed IV Catheter System with NearPort™ IV Access, achieves its intended use based on the same technology and principles of operation as the predicate device. A comparison of the subject and predicate device technological characteristics is provided in the table below

Attribute	SUBJECT (K231239) Nexiva™ Closed IV Catheter System with NearPort™ IV Access	PREDICATE (K183399) BD Nexiva™ Closed IV Catheter System	Comparison & Discussion
Classification	21 CFR 880.5200 Class II FOZ - Intravascular Catheter FPA – Intravascular Administration Set	21 CFR 880.5200 Class II FOZ - Intravascular Catheter FPA – Intravascular Administration Set	Same

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Attribute	SUBJECT (K231239) Nexiva™ Closed IV Catheter System with NearPort™ IV Access	PREDICATE (K183399) BD Nexiva™ Closed IV Catheter System	Comparison & Discussion
Indications for Use	The Nexiva™ Closed IV Catheter System with NearPort™ IV Access is intended to be inserted into a patient's peripheral venous system for short term use to administer fluids and/or medications and to sample blood. 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 24-18 GA (0.7-1.3 mm) devices are suitable for use with power injectors set to a maximum pressure of 300 psi (2068 kPa) when connected to the NearPort™ IV Access.	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.	Modifications have been made to re-phrase and align with product use specifications. The Indications for Use is being narrowed to limit use to the peripheral venous system only to administer fluids and/or medications and to sample blood. Narrowing the Indications for Use does not raise any new or different questions of safety or effectiveness. Additionally, power injection capability has been expanded to include the 24 GA configuration, using the same test method as the predicate device as supported by performance verification testing, which did not raise any new or different questions of safety and effectiveness.
Intended Use	Intravascular access	Intravascular access	Same
Fundamental Scientific Technology	Closed peripheral intravenous catheter system designed with an integrated extension tubing incorporating a Y (dual)-port injection site. Incorporates Instaflash™ technology to assist with flashback visualization. Nexiva™ Closed IV Catheter System with NearPort™ IV Access is compatible with the PIVO™ Pro Needle-free Blood Collection	Closed peripheral intravascular catheter system designed with an integrated extension set incorporating a single port or Y (dual)-port injection site. Incorporates Instaflash™ technology to assist with flashback visualization	The subject device uses the same fundamental technology compared to the predicate device (K183399). The NearPort™ IV Access component has the same fundamental scientific technology as the predicate;

Attribute	SUBJECT (K231239) Nexiva™ Closed IV Catheter System with NearPort™ IV Access	PREDICATE (K183399) BD Nexiva™ Closed IV Catheter System	Comparison & Discussion
	Device for needle-free blood draws.		however, the split septum design enables compatibility with a needle-free blood draw device as supported by human factors validation testing, which did not raise any new or different questions of safety and effectiveness.
Primary Components Material Composition			
ISO 10993-1 Biocompatibility Contact Type and Duration	Body Contact: Externally communicating device Contact: Circulating blood Contact Duration: Limited (A) to Prolonged (B) (≤ 24 hrs to 30 days)	Body Contact: Externally communicating device Contact: Circulating blood Contact Duration: Limited (A) to Prolonged (B) (≤ 24 hrs to 30 days)	Same
Needle	Stainless Steel	Stainless Steel	Same
Catheter Tubing	Polyurethane with radiopaque barium sulfate	Polyurethane with radiopaque barium sulfate	Same
Grip	Polycarbonate + White Colorant	Polycarbonate + White Colorant	Same
Tip Shield	Polycarbonate + Gray Colorant	Polycarbonate + Gray Colorant	Same
Catheter Adapter	Copolyester	Copolyester	The material formulation has been modified; however, the material resin type remains the same. Testing in accordance with ISO 10993-1 requirements did not raise any new or different questions related to biological safety
Catheter Adapter Wings	Thermoplastic Elastomer + Gauge Specific Colorant Green (18 GA) Pink (20 GA) Blue (22 GA) Yellow (24 GA)	Thermoplastic Elastomer + Gauge Specific Colorant Green (18 GA) Pink (20 GA) Blue (22 GA) Yellow (24 GA)	A modified Shore A durometer is used in the subject device but maintains the same base resins and colorants, except a new green colorant

Attribute	SUBJECT (K231239) Nexiva™ Closed IV Catheter System with NearPort™ IV Access	PREDICATE (K183399) BD Nexiva™ Closed IV Catheter System	Comparison & Discussion
			supplier has been qualified. Testing in accordance with ISO 10993-1 requirements did not raise any new or different questions related to biological safety.
Extension Tubing	Thermoplastic Polyurethane	Thermoplastic Polyurethane	Same
Straight Luer Adapter	Copolyester	Copolyester	Same
Pinch Clamp	Acetal Copolymer	Acetal Copolymer	Same
MaxZero™	Polycarbonate / Silicone	Polycarbonate / Silicone	Same
NearPort™ IV Access	Polycarbonate / Silicone	N/A ± not part of predicate device design	Polymer material family is same as other needle-free connectors offered with predicate device.
Catheter Dimensions	Catheter Diameters 18 GA, 20 GA, 22 GA, 24 GA Catheter Lengths 0.75 IN, 1.00 IN, 1.25 IN, 1.75 IN	Catheter Diameters 18 GA, 20 GA, 22 GA, 24 GA Catheter Lengths 0.56 IN, 0.75 IN, 1.00 IN, 1.25 IN, 1.75 IN	A 24 GA x 0.56 IN product configuration is not part of the subject device submission; however, all other configurations (e.g., Gauge and Length) are within the bounds of the predicate device, which does not raise any new or different questions of safety and effectiveness (i.e., performance testing).
Product Configurations	• NearPort IV Access	• Single Port • Single Port with MaxZero • Dual Port • Dual Port with Q-Syte • Dual Port with Q-Syte and End Cap • Dual Port with MaxZero	NearPort IV Access component is a needle-free connector same as Q-Syte and MaxZero
Sterilization Modality	Ethylene Oxide	Ethylene Oxide	Same

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Minimum SAL	1×10^{-6}	1×10^{-6}	Same
Energy Source	User operated	User operated	Same
Single Use Only	Yes	Yes	Same

Summary of Performance Testing

A Risk Analysis in accordance with ISO 14971:2019 was conducted to assess the impact of the proposed modifications to the predicate device.

Performance tests completed on the subject devices were limited to those tests required to support a determination of substantial equivalence to the predicate device. A risk analysis was conducted to assess the impact of the proposed modifications to the predicate device. 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 predetermined design requirements:

1) Compliance Testing
   - Biocompatibility (ISO 10993-1)
     - Body contact: Externally communicating device
     - Contact: Circulating blood
     - Contact duration: Limited (A) to Prolonged (B) (≤ 24 hrs to 30 days)
   - Sterilization Residuals (ISO 10993-7)
   - Packaging Testing (ASTM D4169)
   - Sterilization Validation (ISO 11135-1)
   - Performance Testing per ISO 10555-1 and ISO 10555-5
     - Peak Tensile Force (ISO 10555-1 §4.6)
     - Liquid Leakage (ISO 10555-1 §4.7.1)
     - Air Leakage (ISO 10555-1 §4.7.2)
     - Gravity Flow Rate (ISO 10555-1 §4.9)
     - Power Injection Flow Rate (ISO 10555-1 §4.10)
   - Needle Safety Testing (ISO 23908)
   - Luer Testing (ISO 594-1 and ISO 594-2)
2) BD Internal Studies
   - Catheter tubing open flow pressure
   - Catheter tubing rupture pressure
   - System burst
   - Catheter adapter separation force
   - Extension tubing detachment force

- Wing bending force
- Needle cover removal force
- Needle cover retention
- Flow control plug retention rate

3) Evaluation of MR Compatibility per *ASTM F2182-19 Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging* and *Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment, Guidance for Industry and Food and Drug Administration Staff,* issued May 2021
4) Evaluation of Microbial Ingress per *Intravascular Administration Sets Premarket Notification Submissions [510(k)] Guidance for Industry and FDA Staff,* issued July 2008
5) Usability testing per *Applying Human Factors and Usability Engineering to Medical Devices Guidance for Industry and Food and Drug Administration Staff,* issued February 2016

Per 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.

Clinical studies are not required to demonstrate substantial equivalence to the predicate device.

Summary of Substantial Equivalence	Based on the indications for use, technological characteristics, and results of performance testing, the subject device, Nexiva™ Closed IV Catheter System with NearPort™ IV Access has been demonstrated to be substantially equivalent to the predicate BD Nexiva™ Closed IV Catheter System