December 1, 2023

Becton Dickinson Infusion Therapy Systems Inc.
Sunny Patel
Senior Regulatory Affairs Specialist
9450 South State Street
Sandy, Utah 84070

Re: K233529
Trade/Device Name: BD Nexiva™ Diffusics™ Closed IV Catheter System with BD MaxZero™ Needle-free Connector
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: Class II
Product Code: FOZ
Dated: November 1, 2023
Received: November 2, 2023

Dear Sunny Patel:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K233529

Device Name
BD Nexiva™ Diffusics™ Closed IV Catheter System with BD MaxZero™ Needle-free Connector

Indications for Use *(Describe)*
The BD Nexiva™ Diffusics™ Closed IV Catheter System is intended to be inserted into a patient's vascular system for short term use to sample blood 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. These devices are suitable for use with power injectors set to a maximum pressure of 325 psi (2240 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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K233529- 510(k) Summary

BD Nexiva™ Diffusics™ Closed IV Catheter System with BD MaxZero™ Needle-free Connector

Date: December 1, 2023

Submitter Information	Submitter Name:	Becton Dickinson Infusion Therapy Systems Inc.
	Submitter Address:	9450 South State Street, Sandy, Utah 84070
	Contact Person:	Sunny Patel, Senior Regulatory Affairs Specialist
	Email Address:	sunny.patel@bd.com
	Phone Number:	(817) 609-9594
Subject Device	Trade Name:	BD Nexiva™ Diffusics™ Closed IV Catheter System with BD MaxZero™ Needle-free Connector
	Common Name:	Peripheral Intravascular or IV Catheter
	510(k) Reference:	K233529
	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
Predicate Device	Trade Name:	BD Nexiva™ Diffusics™ Closed IV Catheter System
	Common Name:	Peripheral Intravascular or IV Catheter
	510(k) Reference:	K173354
	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
Reason for Submission	The purpose of this submission is to introduce the BD Nexiva™ Diffusics™ Closed IV Catheter System with BD MaxZero™ Needle-free Connector.	
Device Description	BD Nexiva™ Diffusics™ Closed IV Catheter Systems are over-the-needle, intravascular (IV) catheters. These devices have a radiopaque BD Vialon™ catheter material with three side holes located near the tip of the catheter which are designed to optimize power injection procedures. These devices also have a needle, needle shield, septum, stabilization platform, integrated extension tubing, clamp, Luer connector, and vent plug. The Luer connector displays gauge specific maximum flow rate and the maximum power injector pressure limit setting. The needle and catheter are protected by a needle cover. An end cap with protective cover is provided in the unit package. A BD MaxZero™ device with protective cover is provided in the unit 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 needle stick 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. 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 BD Nexiva™ Diffusics™ Closed IV Catheter System is intended to be inserted into a patient's vascular system for short term use to sample blood 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. These devices are suitable for use with power injectors set to a maximum pressure of 325 psi (2240 kPa) when access ports not suitable for use with power injectors are removed.
Technological Characteristics	Technological characteristics of the subject BD Nexiva™ Diffusics™ Closed IV Catheter System with BD MaxZero™ Needle-free Connector are substantially equivalent to predicate BD Nexiva™ Diffusics™ Closed IV Catheter System. The subject device 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 BD Nexiva™ Diffusics™ Closed IV Catheter System with BD MaxZero™ Needle-free Connector	PREDICATE (K173354) BD Nexiva™ Diffusics™ Closed IV Catheter System	Comparison
Classification	21 CFR 880.5200 Class II FOZ - Intravascular Catheter	21 CFR 880.5200 Class II FOZ - Intravascular Catheter	Same
Indications for Use	The BD Nexiva™ Diffusics™ Closed IV Catheter Systems are intended to be inserted into a patient's vascular system for short term use to sample blood 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. These devices are suitable for use with power injectors set to a maximum pressure of 325 psi (2240 kPa) when access ports not suitable	The BD Nexiva™ Diffusics™ 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 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. These devices are suitable for use with power injectors set to a maximum pressure of 325 psi (2240 kPa) when access ports not	Substantially Equivalent- The subject and predicate devices are both intended to sample blood and administer fluids. The subject device Indications for Use has been narrowed to remove "monitor blood pressure" compared to the predicate device. Narrowing the Indications for Use does not raise any new or

Attribute	SUBJECT BD Nexiva™ Diffusics™ Closed IV Catheter System with BD MaxZero™ Needle-free Connector	PREDICATE (K173354) BD Nexiva™ Diffusics™ Closed IV Catheter System	Comparison
	for use with power injectors are removed.	suitable for use with power injectors are removed.	different questions of safety or effectiveness.
Intended Use	Intravascular access	Intravascular access	Same
Fundamental Scientific Technology	Closed peripheral intravascular catheter system are 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 are designed with an integrated extension set incorporating a single port injection site. Incorporates BD Instaflash™ technology to assist with flashback visualization	Same
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 (Cannula)	Stainless Steel	Stainless Steel	Same
Catheter Tubing	BD Vialon™ Polyurethane with Barium Sulfate	BD Vialon™ Polyurethane with Barium Sulfate	Same
Catheter Adapter	Copolyester	Copolyester	Same
Catheter Adapter Wings	TPE with Gauge-Specific Colorant	TPE with Gauge-Specific Colorant	Same
Tip Shield	Polycarbonate with Grey Colorant	Polycarbonate with Grey Colorant	Same
Grip/Needle Hub	Polycarbonate with White Colorant	Polycarbonate with White Colorant	Same
Pinch Clamp	Acetal with Blue Colorant	Acetal with Blue Colorant	Same
Extension Tubing	Biomerics Polyurethane	Biomerics Polyurethane	Same
Luer Adapter	Copolyester with Gauge-Specific Colorant	Copolyester with Gauge-Specific Colorant	Same
Luer Adapter Overmold	TPE with Blue Colorant and White Print Ink	TPE with Blue Colorant and White Print Ink	Same
End Cap	Polypropylene with White Colorant	Polypropylene with White Colorant	Same
End Cap Protective Cover	HDPE with Blue Colorant	HDPE with Blue Colorant	Same
Vent Plug	Polypropylene and Acrylic-Nylon Membrane	Polypropylene and Acrylic-Nylon Membrane	Same
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 0.75 IN, 1.00 IN, 1.25 IN	Different- The subject and predicate devices are substantially equivalent. The longer length (1.75 IN) subject device configurations were evaluated using the equivalent test methods as the predicate device.

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Attribute	SUBJECT BD Nexiva™ Diffusics™ Closed IV Catheter System with BD MaxZero™ Needle-free Connector	PREDICATE (K173354) BD Nexiva™ Diffusics™ Closed IV Catheter System	Comparison
			This modification did not raise any new or different questions of safety and effectiveness.
Product Configurations	• Single Port with BD MaxZero™ Needle-free Connector	• Single Port	Different- The subject and predicate devices are offered in the same single port configuration. The BD MaxZero™ Needle-free Connector is included as a kit component in the subject device unit package. The addition of the BD MaxZero™ Needle-free Connector as a kit component does not alter the intended use of the subject device compared to the predicate device.
Sterilization Modality	Ethylene Oxide	Ethylene Oxide	Same
Minimum SAL	1×10^{-6}	1×10^{-6}	Same
Energy Source	User operated	User operated	Same
Disposable or Reusable	Disposable	Disposable	Same
Single Use Only	Yes	Yes	Same

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Summary of Performance Tests	A Risk Analysis was conducted in accordance with I*SO 14971, Medical Devices – Risk Management for Medical Devices* was conducted to assess the impact of the proposed modifications to the predicate BD Nexiva™ Diffusics™ Closed IV Catheter System. 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: • Sterilization Residuals (ISO 10993-7) • Biocompatibility (ISO 10993-1) • Packaging Testing ISO 11607-1 - Aseptic Presentation Test (ISO 11607-1, Section 7) - Simulated Shipping Conditioning (ISO 11607-1, Section 8) - Bubble Leak Detection (Package Integrity) (ISO 11607-1, Section 8) - Package Peel Force Pouch Seal Strength (ISO 11607-1, Section 5.1.8 and 5.1.9c) - Packaging Materials Microbial Barrier (ISO 11607-1, Annex C) - Ink Permanency/Text Legibility (ISO 11607-1, Section 5.4) - Seal Width (ISO 11607-1, Section 5.1.6d; 5.1.8c and 5.1.9d) - Packaging must protect the product from damages (Damage to Device) ISO 11607-1) • Testing in accordance with ISO 10555-1 - Gravity Flow Rate (ISO 10555-1, Section 4.9) - Catheter Burst Pressure (ISO 10555-1, Section 4.10) • Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test) (ASTMF 2096-11) • Standard Test Method for Seal Strength of Flexible Barrier Materials (ASTM F88/F88M-15) • Standard Practice for Performance Testing of Shipping Containers and Systems (ASTM D4169-16) 2) BD Internal Requirements • Open flow pressure • Power injection peak pressure • Catheter stability Per 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 device. 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 BD Nexiva™ Diffusics™ Closed IV Catheter System with BD MaxZero™ Needle-free Connector has been demonstrated to be substantially equivalent to the predicate BD Nexiva™ Diffusics™ Closed IV Catheter System (K173354).