June 3, 2025

Becton Dickinson Infusion Therapy Systems Inc.
Vantana Krishnakumar
Associate Staff Regulatory Affairs Specialist
9450 South State Street
Sandy, Utah 84070

Re: K250682
Trade/Device Name: BD Nexiva™ Diffusics™ Closed IV Catheter System and 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: March 6, 2025
Received: March 6, 2025

Dear Vantana Krishnakumar:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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

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)*
K250682

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

Indications for Use *(Describe)*
BD Nexiva™ Diffusics™ Closed IV Catheter System and BD Nexiva™ Diffusics™ Closed IV Catheter System with MaxZero™ Needle-free Connector

BD Nexiva™ Diffusics™ Closed IV Catheter System is intended to be inserted into a patient's peripheral vascular system for short term use to sample blood, monitor blood pressure or administer fluids. This device 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. This device is 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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K250682 – 510(k) Summary (21 CFR §807.92)
BD Nexiva™ Diffusics™ Closed IV Catheter System
and BD Nexiva™ Diffusics™ Closed IV Catheter System
with BD MaxZero™ Needle-free Connector

Submitter Information	Submitter Name:	Becton Dickinson Infusion Therapy Systems Inc.
	Submitter Address:	9450 South State Street, Sandy, Utah 84070
	Contact Person:	Vantana Krishnakumar, Associate Staff Regulatory Affairs Specialist
	Email Address:	vantana.krishnakumar@bd.com
	Phone Number:	801-522-5000
	Date of Preparation:	May 08, 2025
Subject Devices	Trade Name:	BD Nexiva™ Diffusics™ 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
	Classification Panel:	General Hospital
	Trade Name:	BD Nexiva™ Diffusics™ Closed IV Catheter System with BD MaxZero™ Needle-free Connector
	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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Predicate Devices	Trade Name:	BD Nexiva™ Diffusics™ Closed IV Catheter System
	510(k) Reference:	K173354
	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

Note: K173354 serves as the Predicate device for the subject device BD Nexiva™ Diffusics™ Closed IV Catheter System

Trade Name:	BD Nexiva™ Diffusics™ Closed IV Catheter System with BD MaxZero™ Needle-free Connector
510(k) Reference:	K233529
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

Note: K233529 serves as the Predicate device for the subject device BD Nexiva™ Diffusics™ Closed IV Catheter System with BD MaxZero™ Needle-free Connector

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Device Description	BD Nexiva™ Diffusics™ Closed IV Catheter Systems (Nexiva Diffusics) and BD Nexiva™ Diffusics™ Closed IV Catheter System with BD MaxZero™ Needle-free Connector (Nexiva Diffusics with Max Zero) 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 for BD Nexiva™ Diffusics™ Closed IV Catheter System with BD MaxZero™ Needle-free Connector kit.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).

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Indications for Use (21 CFR § 807.92(a)(5))	**BD Nexiva™ Diffusics™ Closed IV Catheter System and BD Nexiva™ Diffusics™ Closed IV Catheter System with MaxZero™ Needle-free Connector** BD Nexiva™ Diffusics™ Closed IV Catheter System is intended to be inserted into a patient's peripheral vascular system for short term use to sample blood, monitor blood pressure or administer fluids. This device 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. This device is 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.
Purpose of this submission	• Updating the indications for use for the Nexiva Diffusics with Max Zero to include blood pressure monitoring indication. • Updated packaging for the subject devices Nexiva Diffusics and Nexiva Diffusics with Max Zero. • Luer lock performance testing per ISO 80369-7:2021. • Updated performance specifications related to blood pressure monitoring and blood sampling
Technological Characteristics	Technological characteristics of the subject devices are substantially equivalent to their predicate device. The subject BD Nexiva™ Diffusics™ Closed IV Catheter System and BD Nexiva™ Diffusics™ Closed IV Catheter System with BD MaxZero™ Needle-free Connector achieve their intended use based on the same technology and principles of operation as the predicate devices K173354 and K233529, respectively.

Note: Highlighted **blue text** indicates differences from the predicate device.

Attribute	SUBJECT **BD Nexiva™ Diffusics™ Closed IV Catheter System**	PREDICATE (K173354) **BD Nexiva™ Diffusics™ Closed IV Catheter System**	**Substantially Equivalent?**
Classification	21 CFR 880.5200 Class II FOZ - Intravascular Catheter	21 CFR 880.5200 Class II FOZ - Intravascular Catheter	Yes Same as predicate.
Indications for Use	BD Nexiva™ Diffusics™ Closed IV Catheter **System is** intended to be inserted into a patient's **peripheral** vascular system for short term use to sample blood, monitor blood pressure, or	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	Yes Same as predicate. The word "peripheral" has been added for clarification only with no change to the substance, meaning or

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Attribute	SUBJECT BD Nexiva™ Diffusics™ Closed IV Catheter System	PREDICATE (K173354) BD Nexiva™ Diffusics™ Closed IV Catheter System	Substantially Equivalent?
	administer fluids. **This device** 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. **This device is** 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.	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.	scope of the intended use of the device. Additional minor wording changes with no change to the substance, meaning or scope.
Fundamental Scientific Technology	Closed peripheral intravascular catheter systems are designed with an integrated extension set incorporating a single port injection site. Incorporates BD Instaflash™ technology to assist with flashback visualization. In addition, the catheter tip includes diffuser holes to reduce the velocity of contrast media exiting the catheter tip during CT scans.	Closed peripheral intravascular catheter systems are designed with an integrated extension set incorporating a single port injection site. Incorporates BD Instaflash technology to assist with flashback visualization. In addition, the catheter tip includes diffuser holes to reduce the velocity of contrast media exiting the catheter tip during CT scans.	Yes Added trademark symbol (™) to Instaflash, which has no impact to technological characteristics
Catheter Dimensions	Catheter Diameters 18 GA, 20 GA, 22 GA, 24 GA Catheter Lengths 0.75 IN, 1.00 IN, 1.25 IN	Catheter Diameters 18 GA, 20 GA, 22 GA, 24 GA Catheter Lengths 0.75 IN, 1.00 IN, 1.25 IN	Yes Same as predicate
Product Configurations	Single Port	Single Port	Yes Same as predicate
Sterilization Modality	Ethylene Oxide	Ethylene Oxide	Yes Same as predicate.
Minimum SAL	1×10^{-6}	1×10^{-6}	Yes Same as predicate.

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Attribute	SUBJECT BD Nexiva™ Diffusics™ Closed IV Catheter System with BD MaxZero™ Needle-free Connector	PREDICATE (K233529) BD Nexiva™ Diffusics™ Closed IV Catheter System with BD MaxZero™ Needle-free Connector	Substantially Equivalent?
Classification	21 CFR 880.5200 Class II FOZ - Intravascular Catheter	21 CFR 880.5200 Class II FOZ - Intravascular Catheter	Yes Same as predicate.
Indications for Use	BD Nexiva™ Diffusics™ Closed IV Catheter **System is** intended to be inserted into a patient's **peripheral** vascular system for short term use to sample blood, **monitor blood pressure**, or administer fluids. **This device** 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. **This device is** 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.	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 for use with power injectors are removed.	Yes Addition of 'monitor blood pressure' in the Indications for Use as the evidence is established since the last predicate submission. BD Nexiva Diffusics closed IV catheter system and BD Nexiva™ Diffusics™ Closed IV Catheter System with BD MaxZero™ Needle-free Connector have the same materials, intended uses and Indications of use. This addition to the Indications for Use to BD Nexiva™ Diffusics™ Closed IV Catheter System with BD MaxZero™ Needle-free Connector does not raise any new or different questions of safety or effectiveness as demonstrated by kink resistance and frequency response performance testing. The word "peripheral" has been added for clarification only with no change to the substance, meaning or scope of the intended use of the device. Additional minor wording changes with no change to the substance, meaning or scope.

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Attribute	SUBJECT BD Nexiva™ Diffusics™ Closed IV Catheter System with BD MaxZero™ Needle-free Connector	PREDICATE (K233529) BD Nexiva™ Diffusics™ Closed IV Catheter System with BD MaxZero™ Needle-free Connector	Substantially Equivalent?
Fundamental Scientific Technology	Closed peripheral intravascular catheter systems are designed with an integrated extension set incorporating a single port injection site. Incorporates BD Instaflash™ technology to assist with flashback visualization. In addition, the catheter tip includes diffuser holes to reduce the velocity of contrast media exiting the catheter tip during CT scans.	Closed peripheral intravascular catheter systems are designed with an integrated extension set incorporating a single port injection site. Incorporates BD Instaflash™ technology to assist with flashback visualization. In addition, the catheter tip includes diffuser holes to reduce the velocity of contrast media exiting the catheter tip during CT scans.	Yes Same as predicate
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, 1.75 IN	Yes Same as predicate
Product Configurations	Single Port with BD MaxZero™ Needle-free Connector	Single Port with BD MaxZero™ Needle-free Connector	Yes Same as predicate
Sterilization Modality	Ethylene Oxide	Ethylene Oxide	Yes Same as predicate.
Minimum SAL	1×10^{-6}	1×10^{-6}	Yes Same as predicate.

NOTE: Highlighted **blue text** indicates differences from the predicate device.

Comparison of Subject / Predicate Sterile Packaging Materials			
Packaging Component	**SUBJECT** **BD Nexiva™ Diffusics™ Closed IV Catheter System**	**PREDICATE** **BD Nexiva™ Diffusics™ Closed IV Catheter System (K173354)**	**Substantially Equivalent?**
Top Web Material	PS 75 Medical paper	PS 75 Medical paper	Yes Same as predicate
Bottom Web Material	PETG 16 mil Copolyester or **PETG [MED-G] 10 mil or 16 mil Copolyester**	PETG 16 mil Copolyester or PETG [MED-G] 16 mil Copolyester	Yes A change was made to the bottom web material formulation and bottom web thickness. The results of performance testing demonstrate that the subject device performs as intended.

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Comparison of Subject / Predicate Sterile Packaging Materials			
Packaging Component	**SUBJECT BD Nexiva™ Diffusics™ Closed IV Catheter System**	**PREDICATE BD Nexiva™ Diffusics™ Closed IV Catheter System (K173354)**	**Substantially Equivalent?**
			This change does not raise any new or different questions of safety or effectiveness.
Dispenser Box	Cardboard Clay Coated Newsback Linder Board or Solid Bleached Sulfate or **Coated Recycled Board / Coated Kraft Back**	Cardboard Clay Coated Newsback Linder Board or Solid Bleached Sulfate	Yes A change was made to the dispenser box material and thickness. The results of performance testing demonstrate that the subject device performs as intended. This change does not raise any new or different questions of safety or effectiveness.
Shipper Box	Corrugated (Liner/medium single wall board)	Corrugated (Liner/medium single wall board)	Yes Same as predicate
Printed Top Web Colorant (Fixed / Variable)	Black + Gauge Specific Colorant: Green Pink Blue Yellow	Black + Gauge Specific Colorant: Green Pink Blue Yellow	Yes Same as predicate

Comparison of Subject / Predicate Sterile Packaging Materials			
Packaging Component	**SUBJECT BD Nexiva™ Diffusics™ Closed IV Catheter System with MaxZero™**	**PREDICATE BD Nexiva™ Diffusics™ Closed IV Catheter System with MaxZero™ (K233529)**	**Substantially Equivalent?**
Top Web Material	PS 75 Medical paper	PS 75 Medical paper	Yes Same as predicate

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Comparison of Subject / Predicate Sterile Packaging Materials			
Packaging Component	**SUBJECT BD Nexiva™ Diffusics™ Closed IV Catheter System with MaxZero™**	**PREDICATE BD Nexiva™ Diffusics™ Closed IV Catheter System with MaxZero™ (K233529)**	**Substantially Equivalent?**
Bottom Web Material	PETG 16 mil Copolyester or **PETG [MED-G] 10 mil or 16 mil Copolyester**	PETG 16 mil Copolyester or PETG [MED-G] 16 mil Copolyester	Yes A change was made to the bottom web material formulation and bottom web thickness. The results of performance testing demonstrate that the subject device performs as intended. This change does not raise any new or different questions of safety or effectiveness.
Dispenser Box	Cardboard Clay Coated Newsback Linder Board or Solid Bleached Sulfate or **Coated Recycled Board / Coated Kraft Back**	Cardboard Clay Coated Newsback Linder Board or Solid Bleached Sulfate	Yes A change was made to the dispenser box material and thickness. The results of performance testing demonstrate that the subject device performs as intended. This change does not raise any new or different questions of safety or effectiveness.
Shipper Box	Corrugated (Liner/medium single wall board)	Corrugated (Liner/medium single wall board)	Yes Same as predicate
Printed Top Web Colorant (Fixed / Variable)	Black + Gauge Specific Colorant: Green Pink Blue Yellow	Black + Gauge Specific Colorant: Green Pink Blue Yellow	Yes Same as predicate

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Comparison of Subject / Predicate Device Primary Device Component Materials				
Attribute	**Component**	**SUBJECT BD Nexiva™ Diffusics™ Closed IV Catheter System**	**PREDICATE BD Nexiva™ Diffusics™ Closed IV Catheter System (K173354)**	**Substantially Equivalent?**
Materials	Needle Cover	LDPE	LDPE	Yes
	Needle (Cannula)	Stainless Steel	Stainless Steel	Yes
	Needle Adhesive (Cannula Adhesive)	Acrylated Urethane	Acrylated Urethane	Yes
	Needle Lubricant (Cannula Lubricant)	Silicone	Silicone	Yes
	Catheter Tubing	BD Vialon™ Polyurethane with Barium Sulfate	BD Vialon™ Polyurethane with Barium Sulfate	Yes
	Catheter Lubricant	Silicone	Silicone	Yes
	Catheter Tipping Lubricant	Silicone	Silicone	Yes
	Catheter Adapter Wings	TPE with Gauge-Specific Colorant	TPE with Gauge-Specific Colorant	Yes
	Catheter Adapter	Copolyester	Copolyester	Yes
	Wedge	Stainless Steel	Stainless Steel	Yes
	Septum Canister	Copolyester with Grey Colorant	Copolyester with Grey Colorant	Yes
	Septum	Polyisoprene	Polyisoprene	Yes
	V-Clip	Stainless Steel with Parylene Coating	Stainless Steel with Parylene Coating	Yes
	Retention Washer	Stainless Steel	Stainless Steel	Yes
	Tip Shield	Polycarbonate with Grey Colorant	Polycarbonate with Grey Colorant	Yes
	Grip/Needle Hub	Polycarbonate with White Colorant	Polycarbonate with White Colorant	Yes
	Pinch Clamp	Acetal with Blue Colorant	Acetal with Blue Colorant	Yes
	Extension Tubing	Thermoplastic Polyurethane	Biomerics Polyurethane **NOTE:** Biomerics is a supplier and not the type of polymer. This is corrected in the subject device submission with no change to material formulation	Yes
	Extension Tubing Adhesive	UV Cured Acrylic	Loctite **NOTE:** Loctite is a supplier and not the type of adhesive. This is corrected in the subject device submission with no change to material formulation	Yes
	Luer Adapter	Copolyester with Gauge- Specific Colorant	Copolyester with Gauge-Specific Colorant	Yes
	Luer Adapter Overmold	TPE with Blue Colorant and White Print Ink	TPE with Blue Colorant and White Print Ink	Yes

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Comparison of Subject / Predicate Device Primary Device Component Materials				
Attribute	**Component**	**SUBJECT BD Nexiva™ Diffusics™ Closed IV Catheter System**	**PREDICATE BD Nexiva™ Diffusics™ Closed IV Catheter System (K173354)**	**Substantially Equivalent?**
	End Cap	Polypropylene with White Colorant	Polypropylene with White Colorant	Yes
	End Cap Protective Cover	HDPE with Blue Colorant	HDPE with Blue Colorant	Yes
	Vent Plug	Polypropylene and Acrylic-Nylon Membrane	Polypropylene and Acrylic- Nylon Membrane	Yes

Comparison of Subject / Predicate Device Primary Device Component Materials				
Attribute	**Component**	**SUBJECT BD Nexiva™ Diffusics™ Closed IV Catheter System with MaxZero™ Needle-free Connector**	**PREDICATE BD Nexiva™ Diffusics™ Closed IV Catheter System with MaxZero™ Needle-free Connector (K233529)**	**Substantially Equivalent?**
Materials	Needle Cover	LDPE	LDPE	Yes
	Needle (Cannula)	Stainless Steel	Stainless Steel	Yes
	Needle Adhesive (Cannula Adhesive)	Acrylated Urethane	Acrylated Urethane	Yes
	Needle Lubricant (Cannula Lubricant)	Silicone	Silicone	Yes
	Catheter Tubing	BD Vialon™ Polyurethane with Barium Sulfate	BD Vialon™ Polyurethane with Barium Sulfate	Yes
	Catheter Lubricant	Silicone	Silicone	Yes
	Catheter Tipping Lubricant	Silicone	Silicone	Yes
	Catheter Adapter Wings	TPE with Gauge-Specific Colorant	TPE with Gauge-Specific Colorant	Yes
	Catheter Adapter	Copolyester	Copolyester	Yes
	Wedge	Stainless Steel	Stainless Steel	Yes
	Septum Canister	Copolyester with Grey Colorant	Copolyester with Grey Colorant	Yes
	Septum	Polyisoprene	Polyisoprene	Yes
	V-Clip	Stainless Steel with Parylene Coating	Stainless Steel with Parylene Coating	Yes
	Retention Washer	Stainless Steel	Stainless Steel	Yes
	Tip Shield	Polycarbonate with Grey Colorant	Polycarbonate with Grey Colorant	Yes
	Grip/Needle Hub	Polycarbonate with White Colorant	Polycarbonate with White Colorant	Yes

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Comparison of Subject / Predicate Device Primary Device Component Materials				
Attribute	**Component**	**SUBJECT BD Nexiva™ Diffusics™ Closed IV Catheter System with MaxZero™ Needle-free Connector**	**PREDICATE BD Nexiva™ Diffusics™ Closed IV Catheter System with MaxZero™ Needle-free Connector (K233529)**	**Substantially Equivalent?**
	Pinch Clamp	Acetal with Blue Colorant	Acetal with Blue Colorant	Yes
	Extension Tubing	Thermoplastic Polyurethane	Biomerics Polyurethane **NOTE:** Biomerics is a supplier and not the type of polymer. This is corrected in the subject device submission with no change to material formulation	Yes
	Extension Tubing Adhesive	UV Cured Acrylic	Loctite **NOTE:** Loctite is a supplier and not the type of adhesive. This is corrected in the subject device submission with no change to material formulation	Yes
	Luer Adapter	Copolyester with Gauge- Specific Colorant	Copolyester with Gauge-Specific Colorant	Yes
	Luer Adapter Overmold	TPE with Blue Colorant and White Print Ink	TPE with Blue Colorant and White Print Ink	Yes
	End Cap	Polypropylene with White Colorant	Polypropylene with White Colorant	Yes
	End Cap Protective Cover	HDPE with Blue Colorant	HDPE with Blue Colorant	Yes
	Vent Plug	Polypropylene and Acrylic-Nylon Membrane	Polypropylene and Acrylic- Nylon Membrane	Yes

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Summary of 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 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/representative devices were applied to the subject devices. The performance tests listed below were conducted to ensure that the subject devices meet specified design requirements per BD internal requirements and standards as applicable: BD Internal Requirements Testing: • Frequency Response Testing • Kink Resistance Testing • Blood Fill Time Testing Compliance with Standards Testing: ISO 80369-7 Testing • ISO 80369-7 Second edition 2021-05; Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications Packaging Testing • ISO 11607-1 Second edition 2019-02 - Packaging for terminally sterilized medical devices - Part 1: Requirements for materials sterile barrier systems and packaging systems • ASTM F2096-11 (Reapproved 2019) - Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test) • ASTM F88/F88M-15 - Standard Test Method for Seal Strength of Flexible Barrier Materials 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™ Diffusics™ Closed IV Catheter System has been demonstrated to be substantially equivalent to the predicate device, K173354 and BD Nexiva™ Diffusics™ Closed IV Catheter System with BD MaxZero™ Needle-free Connector has been demonstrated to be substantially equivalent to the predicate device, K233529.