



July 25, 2025

Becton Dickinson Infusion Therapy Systems Inc.
Amy Moore
Staff Regulatory Affairs Associate
9450 South State Street
Sandy, Utah 84070

Re: K243403

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
Dated: June 18, 2025
Received: June 18, 2025

Dear Amy Moore:

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,


David Wolloscheck -S

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

Indications for Use

Submission Number (if known)

K243403

Device Name

BD Nexiva™ Closed IV Catheter System

Indications for Use (Describe)

BD Nexiva™ Closed IV Catheter System - Single Port

BD Nexiva™ 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. 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 - Dual Port

BD Nexiva™ Closed IV Catheter System is intended to be inserted into a patient's peripheral 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. 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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K243403 - 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, Utah 84070
	Contact Person:	Amy Moore, Staff Regulatory Affairs Specialist
	Email Address:	amy.moore@bd.com
	Phone Number:	(801) 522-5200
	Date of Preparation:	July 25, 2025
Subject Device	Trade Name:	BD Nexiva™ Closed IV Catheter System
	Common Name:	Short-term, less than 30 days, intravascular, therapeutic 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	Trade Name:	BD Nexiva™ Closed IV Catheter System
	510(k) Reference:	K183399
	Common Name:	Short-term, less than 30 days, intravascular, therapeutic catheter
	Regulation Number:	21 CFR 880.5200
	Regulation Name:	Intravascular catheter
	Regulatory Class:	II
	Product Code:	FOZ (Primary); FPA (Secondary)
	Classification Panel:	General Hospital
Reason for Submission	The purpose of this submission is to notify the FDA of the following:	
	<ul style="list-style-type: none">• Defined or modified performance specifications for Blood Fill Time (Blood Sampling), Frequency Response (Blood Pressure Monitoring), Catheter Kink Resistance (Blood Pressure Monitoring), and ISO 80369-7 (in place of ISO 594-1 and ISO 594-2);• Narrowed Indications for Use for dual ported configurations to limit use to the peripheral venous system only to administer fluids and/or medications and sample blood.	
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 needle-free connector (BD Q-Syte™ or BD MaxZero™) (dual port configurations only). The needle and catheter are protected by a needle cover. A BD Q-Syte™ Needle-free Connector, BD MaxZero™ Needle-free Connector, 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))

BD Nexiva™ Closed IV Catheter System - Single Port

BD Nexiva™ 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. 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 - Dual Port

BD Nexiva™ Closed IV Catheter System is intended to be inserted into a patient's peripheral 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. 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 device are substantially equivalent to the predicate device. The subject BD Nexiva™ Closed IV Catheter 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™ Closed IV Catheter System	PREDICATE (K183399) BD Nexiva™ Closed IV Catheter System	Substantially Equivalent?
Classification	21 CFR 880.5200 Class II FOZ - Intravascular Catheter (primary) FPA – IV Administration Set (secondary)	21 CFR 880.5200 Class II FOZ - Intravascular Catheter (primary) FPA – IV Administration Set (secondary)	Same as the predicate.
Indications for Use – Single Port Configurations	BD Nexiva™ 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. 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 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.	Same as the predicate. The addition of 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.
Indications for Use – Dual Port Configurations	BD Nexiva™ Closed IV Catheter System is intended to be inserted into a patient’s peripheral 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. 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)	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	The Indications for Use for the BD Nexiva Closed IV Catheter System – Dual Port is being narrowed only to sample blood or administer fluids. The addition of 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

	when access ports not suitable for use with power injectors are removed. Note: Blood pressure monitoring has been removed from Indications for Use.	pressure of 300 psi (2068 kPa) when access ports not suitable for use with power injectors are removed.	with no change to the substance, meaning or scope.
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 Instaflash™ needle 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 Instaflash™ needle technology to assist with flashback visualization	Same as predicate.
Catheter Dimensions	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	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	Same as predicate
Product Configurations	<ul style="list-style-type: none"> • Single Port • Single Port with MaxZero™ • Dual Port with Q-Syte™ • Dual Port with Q-Syte™ and End Cap • Dual Port with MaxZero™ 	<ul style="list-style-type: none"> • Single Port • Single Port with MaxZero™ • Dual Port with Q-Syte™ • Dual Port with Q-Syte™ and End Cap • Dual Port with MaxZero™ 	Same as predicate
Sterilization Modality	Ethylene Oxide	Ethylene Oxide	Same as predicate
Comparison of Subject / Predicate Device Primary Device Component Materials			
Needle Cover	LDPE	LDPE	Same as predicate
Needle	Stainless Steel	Stainless Steel	There is no change to the material type; however, the grade of the stainless steel was modified. This change does not raise any new or different questions of safety or effectiveness.
Catheter Tubing	Polyurethane + Barium Sulfate	Polyurethane + Barium Sulfate	Same as predicate
Catheter Adapter Wings	Thermoplastic Elastomer + Gauge-Specific Colorant 24GA (Yellow) 22GA (Blue) 20GA (Pink) 18GA (Green)	Thermoplastic Elastomer + Gauge-Specific Colorant 24GA (Yellow) 22GA (Blue) 20GA (Pink) 18GA (Green)	Same as predicate
Catheter Adapter	Copolyester	Copolyester	Same as predicate

Wedge	Stainless Steel	Stainless Steel	Same as predicate
Septum Canister	Copolyester + Grey Colorant	Copolyester + Grey Colorant	Same as predicate
V-Clip	Stainless Steel with Parylene Coating	Stainless Steel with Parylene Coating	Same as predicate
Retention Washer	Stainless Steel	Stainless Steel	Same as predicate
Tip Shield	Polycarbonate + Grey Colorant	Polycarbonate + Grey Colorant	Same as predicate
Grip / Needle Hub	Polycarbonate + White Colorant	Polycarbonate + White Colorant	Same as predicate
Pinch Clamp	Acetal Copolymer	Acetal Copolymer	Same as predicate
Extension Tubing	Polyurethane	Polyurethane	Same as predicate
Vent Plug	Polypropylene + Acrylic Copolymer Filter	Polypropylene and Acrylic Copolymer Member	Same as predicate
Luer Adapter	Copolyester + Gauge-Specific Colorant	Copolyester + Gauge-Specific Colorant	Same as predicate
End Cap	Polypropylene + White Colorant	Polypropylene + White Colorant	Same as predicate
End Cap Protective Cover	HDPE + Blue Colorant	HDPE + Blue Colorant	Same as predicate
Q-Syte	Polycarbonate + Silicone with Parylene coating	Polycarbonate	Same as predicate
Q-Syte Protective Cover	Polypropylene + Blue Colorant	Polypropylene + Blue Colorant	Same as predicate
MaxZero	Polycarbonate + Silicone	Polycarbonate	Same as predicate
MaxZero Protective Cover	HDPE Polyethylene	HDPE Polyethylene	Same as predicate

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 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 specified design requirements:

- Frequency Response Testing,
 - Kink Resistance Testing,
 - Blood Fill Time Testing,
 - ISO 80369-7 Testing, and
 - ISO 11607-1 Testing.
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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 device.
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