July 11, 2025

Becton Dickinson Infusion Therapy Systems Inc.
Adrian Vidriales-Estrada
Senior Regulatory Affairs Specialist
9450 South State Street
Sandy, Utah 84070

Re: K251155
Trade/Device Name: BD Cathena™ Safety IV Catheter
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular catheter
Regulatory Class: Class II
Product Code: FOZ
Dated: April 14, 2025
Received: April 14, 2025

Dear Adrian Vidriales-Estrada:

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

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)*
K251155

Device Name
BD Cathena™ Safety IV Catheter

Indications for Use *(Describe)*
BD Cathena™ Safety IV Catheter 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).

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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9450 South State Street
Sandy, Utah 84070 USA

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K251155
510(k) Summary (21 CFR §807.92)
BD Cathena™ Safety IV Catheter

Submitter Information	Submitter Name:	Becton Dickinson Infusion Therapy Systems Inc.
	Submitter Address:	9450 South State Street Sandy, Utah 84070
	Contact Person:	Adrian Vidriales-Estrada Sr. Regulatory Affairs Specialist
	Email Address:	adrian.vidriales-estrada@bd.com
	Phone Number:	(801) 750-9654
	Date of Preparation:	June 25, 2025
Subject Device	Trade Name:	BD Cathena™ Safety IV Catheter
	Common Name:	Catheter, intravascular, therapeutic, short-term less than 30 days
	Regulation Number:	21 CFR §880.5200
	Regulation Name:	Intravascular catheter
	Regulatory Class:	II
	Product Code:	FOZ
	Classification Panel:	General Hospital
Predicate Device	Trade Name:	BD Cathena™ Safety IV Catheter
	510(k) Reference:	K220584
	Common Name:	Catheter, intravascular, therapeutic, short-term less than 30 days
	Regulation Number:	21 CFR §880.5200
	Regulation Name:	Intravascular catheter
	Regulatory Class:	II
	Product Code:	FOZ
	Classification Panel:	General Hospital
Reason for Submission	The purpose of this submission is to notify the FDA of the following change: • Creation of new performance specifications for Blood Fill Time to support blood sampling in the current indications for use statement for BD Cathena™ Safety IV Catheter. • Creation of new performance specifications for Frequency Response and Catheter Kink Resistance to support blood pressure monitoring in the current indications for use statement for BD Cathena™ Safety IV Catheter.	

	• Revised IFU to clarify potential complications, warnings, precautions and instructions related to the blood pressure monitoring and arterial use.
Device Description	BD Cathena™ Safety IV Catheter is an over-the-needle, intravascular (IV) catheter. This device includes a radiopaque BD Vialon™ catheter, a needle, a grip, a passive safety needle shield, and a flash chamber with removable vent plug. The needle and catheter are protected by a needle cover. BD Cathena™ Safety IV Catheter has BD Instaflash™ Needle Technology, allowing for immediate visualization of blood along the catheter. The flash chamber provides confirmation that the device has entered the vessel. The needle tip is passively protected when the needle is removed, reducing the risk of accidental needlestick injury. BD Cathena™ Safety IV Catheter is available with or without multi-access BD Multiguard™ Technology, which is designed to stop the flow of blood from the catheter hub until a Luer connection is made. Once a connection is made, fluids or blood can flow through the catheter hub in either direction. BD Cathena™ Safety IV Catheter is available with or without 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, 16 GA (1.7 mm) = Grey).
Indications for Use (21 CFR § 807.92(a)(5))	The subject device Indications for Use is identical to the predicate BD Cathena™ Safety IV Catheter. *BD Cathena™ Safety IV Catheter 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).*
Technological Characteristics	Technological characteristics of the subject device are substantially equivalent to the predicate device. The subject BD Cathena™ Safety 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.

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Attribute	SUBJECT BD Cathena™ Safety IV Catheter	PREDICATE (K220584) BD Cathena™ Safety IV Catheter	Comparison
Classification	21 CFR §880.5200 Class II FOZ - Intravascular Catheter	21 CFR §880.5200 Class II FOZ - Intravascular Catheter	Identical
Fundamental Scientific Technology	Peripheral intravascular catheter designed with a passive needlestick safety mechanism and a multi-use blood control septum (offered with or without this technology). Incorporates BD Instaflash™ Technology to assist with flashback visualization.	Peripheral intravascular catheter designed with a passive needlestick safety mechanism and a multi-use blood control septum (offered with or without this technology). Incorporates BD Instaflash™ Technology to assist with flashback visualization.	Identical
Primary Components Material Composition	Safety Shield Acrylonitrile Butadiene Styrene + White Colorant Grip / Needle Hub Polypropylene Needle, Safety Clip, Wedge & Safety Washer Stainless Steel Catheter Adapter Polypropylene + Colorant 24GA (Yellow) 22GA (Blue) 20GA (Pink) **18GA (Green)** 16GA (Gray) Catheter Tubing Polyurethane with radiopaque barium sulfate Vent Plug Polypropylene Septum Silicone + White Colorant Septum Actuator Polypropylene + White Colorant	Safety Shield Acrylonitrile Butadiene Styrene + White Colorant Grip / Needle Hub Polypropylene Needle, Safety Clip, Wedge & Safety Washer Stainless Steel Catheter Adapter Polypropylene + Colorant 24GA (Yellow) 22GA (Blue) 20GA (Pink) 18GA (Green) 16GA (Gray) Catheter Tubing Polyurethane with radiopaque barium sulfate Vent Plug Polypropylene Septum Silicone + White Colorant Septum Actuator Polypropylene + White Colorant	Substantially Equivalent A new catheter adapter green colorant sub-supplier was qualified. **Previous Supplier:** Green Colorant - Lionel Green 6Y-501, CAS #14302-13-7 **Current Supplier:** Green Colorant – Vynamon, VYG6YFWC, CAS #14302-13-7 No change to colorant formulation and use concentration in the adapter. The modified green pigment maintains the same CAS#14302-13-7, and % concentration. There are no other changes to resin raw materials, processing or technology. A new needle lubricant supplier was qualified. The modified needle lubricant formulation maintains the same chemistry, molecular weight and viscosity. Design verification testing was performed to demonstrate equivalence.

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Attribute	SUBJECT BD Cathena™ Safety IV Catheter	PREDICATE (K220584) BD Cathena™ Safety IV Catheter	Comparison
	Septum Actuator Spring Stainless Steel Lubricants **Silicone**	Septum Actuator Spring Stainless Steel Lubricants Silicone	Biocompatibility data were assessed and adopted from a representative BD device (K201075) utilizing the same intended use, device materials and manufacturing processing,
Catheter Dimensions	Catheter Diameters 16 GA, 18 GA, 20 GA, 22 GA, 24 GA Catheter Lengths 0.75 IN, 1.00 IN, 1.25 IN, 1.75 IN, 2.00 IN	Catheter Diameters 16 GA, 18 GA, 20 GA, 22 GA, 24 GA Catheter Lengths 0.75 IN, 1.00 IN, 1.25 IN, 1.75 IN, 2.00 IN	Identical
Product Configurations	• 16 – 24 GA with BD Multiguard™ Technology • 16 – 24 GA Winged with BD Multiguard™ Technology • 16 and 24 GA without BD Multiguard™ Technology • 16 and 24 GA Winged without BD Multiguard™ Technology	• 16 – 24 GA with BD Multiguard Technology • 16 – 24 GA Winged with BD Multiguard Technology • 16 and 24 GA without BD Multiguard Technology • 16 and 24 GA Winged without BD Multiguard Technology	Identical
Shelf Life	3 years	3 years	Identical
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Identical

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 in accordance with *ISO 14971:2019 Medical Devices – Application of Risk Management to Medical Devices* to determine the impact of the changes on device performance and safety. When technological characteristics between the subject and predicate devices were found to be identical, results of performance testing conducted on the predicate device were applied to the subject device. The performance test listed below was conducted to ensure that the subject device meets pre-determined design requirements:

BD Internal Requirements:

- Frequency Response Testing,
- Kink Resistance Testing,
- Blood Fill Time Testing,
- Average System Drag
- Air Vent Time

	• Procedural Leak Time • Instaflash Time Applicable Standards Requirements: • ISO 11135 and ISO 10993-7 Testing, and • ISO 80369-7 Testing 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 identical indications for use, technological characteristics, and results of performance testing, the subject BD Cathena™ Safety IV Catheter is considered substantially equivalent to the predicate device.