January 24, 2020

Becton Dickinson Infusion Therapy Systems, Inc.
Henry Boland
Staff Regulatory Affairs Specialist
9450 South State Street
Sandy, Utah 84070

Re: K192493
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: December 19, 2019
Received: December 20, 2019

Dear Henry Boland:

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,

for Geeta Pamidimukkala
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192493

Device Name
BD Cathena™ Safety IV Catheter

Indications for Use *(Describe)*
BD Cathena™ Safety IV Catheters are 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. These devices are 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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, UT 84070
	Contact Person:	Henry Boland Staff Regulatory Affairs Specialist
	Email Address:	henry.boland@bd.com
	Phone Number:	(801) 565-2550
	Date of Preparation:	January 23, 2020
Subject Device	Trade Name:	BD Cathena™ Safety IV Catheter
	510(k) Reference:	K192493
	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
Predicate Device	Trade Name:	BD Cathena™ Safety IV Catheter
	510(k) Reference:	K172506, cleared 17 September 2017
	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
Reference Device	Trade Name:	BD Insyte™ Autoguard™ BC Safety IV Catheter
	510(k) Reference:	K110443, cleared 19 July 2011
	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

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	Classification Panel: General Hospital
Reason for Submission	The reason for this submission is the introduction of a performance specification (due to a change in material supplier and grade of silicone lubricant), modification of catheter tubing dimensions, and modifications to product labeling.
Device Description	BD Cathena™ Safety IV Catheters are over-the-needle, intravascular (IV) catheters. These devices include a radiopaque BD Vialon™ catheter, needle, grip, passive safety needle shield, and flash chamber with removable vent plug. The needle and catheter are protected by a needle cover. These devices have 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. These devices are 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. These devices are 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). These devices are not made with natural rubber latex.
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, with the exception that ‘catheters’ was changed to ‘devices’ in some cases. *BD Cathena™ Safety IV Catheters are 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. These devices are suitable for use with power injectors set to a maximum pressure of 325 psi (2240 kPa).*

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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.

The changes to the device include the introduction of a performance specification (due to a change in material supplier and grade of the needle lubricant from a 2-part silicone to 1-part silicone material), modification of catheter tubing dimensions for the 18, 20, 22, and 24G catheters, and modifications to product labeling. There were no changes to the product performance specifications as a result of the catheter tubing dimension changes. Biocompatibility evaluation was performed for the change in silicone, performance testing was performed to support the modifications in the catheter tubing.

A comparison of the subject and predicate device technological characteristics is provided in the table below.

Attribute	SUBJECT BD Cathena™ Safety IV Catheter	PREDICATE (K172506) 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
Indication for Use	BD Cathena™ Safety IV Catheters are 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. These devices are suitable for use with power injectors set to a maximum pressure of 325 psi (2240 kPa).	BD Cathena Safety IV Catheters are 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 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 catheters are suitable for use with power injectors set to a maximum pressure of 325 psi (2240 kPa).	Identical, with the exception that 'catheters' was changed to 'devices' in some cases.

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Attribute	SUBJECT BD Cathena™ Safety IV Catheter	PREDICATE (K172506) BD Cathena™ Safety IV Catheter	Comparison
Fundamental Scientific Technology	Peripheral intravascular catheter designed with a passive needlestick safety mechanism and a multi-use blood control septum. 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. Incorporates BD Instaflash™ technology to assist with flashback visualization.	Identical
Primary Device Components / Materials	Safety Shield Acrylonitrile Butadiene Styrene Grip / Needle Hub Polypropylene Needle Stainless Steel Needle Lubricant 1-part Silicone Catheter Adapter Polypropylene Catheter Tubing Polyurethane with radiopaque barium sulfate	Safety Shield Polystyrene Grip / Needle Hub Polypropylene Needle Stainless Steel Needle Lubricant 2-part Silicone Catheter Adapter Polypropylene Catheter Tubing Polyurethane with radiopaque barium sulfate	Change in safety shield and silicone lubricant materials
Catheter Dimensions	Catheter Diameters 16 G, 18 G, 20 G, 22 G, 24 G Catheter Lengths 0.75 IN, 1.00 IN, 1.25 IN, 1.75 IN, 2.00 IN	Catheter Diameters 16 G, 18 G, 20 G, 22 G, 24 G Catheter Lengths 0.75 IN, 1.00 IN, 1.25 IN, 1.75 IN, 2.00 IN	Change in catheter tubing dimensions for the 18 G, 20 G, 22 G, and 24 G catheters
Shelf-Life	3 years	1 year	Change in shelf life from 1 year to 3 years.

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Attribute	SUBJECT BD Cathena™ Safety IV Catheter	PREDICATE (K172506) BD Cathena™ Safety IV Catheter	Comparison
Sterilization Method	EO (SAL 10^-6)	EO (SAL 10^-6)	Identical

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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 devices. 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 pre-determined design requirements:

BD Internal Specification

- Time to visualize flashback in flash chamber
- Force to break adhesion between catheter unit and needle (initial adhesion)
- Force to remove needle from catheter unit (average system drag)
- Device burst pressure
- Catheter separation force
- Time to visualize flashback in catheter adapter
- Procedural leak time

Standards Compliance

- Flow rate (ISO 10555-1 *Intravascular catheters — Sterile and single-use catheters —Part 1: General requirements*)
- Power injection (ISO 10555-1 *Intravascular catheters — Sterile and single-use catheters —Part 1: General requirements*)

The subject device complies with sterilization requirements of ISO 11135:2014, *Sterilization of Health Care Products – Ethylene Oxide – Part 1: Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices*.

The subject device complies with particulate testing - USP <788> *Particulate Matter in Injections*.

A biocompatibility evaluation, in accordance with 1) ISO 10993-1:2018, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing and 2) FDA guidance *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"* (issued June 16, 2016), was conducted. Biocompatibility data was leveraged from the reference device in addition to performing additional endpoints when required.

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	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.
Summary of Substantial Equivalence	Based on the indications for use, technological characteristics, and results of performance testing, the subject BD Cathena™ Safety IV Catheters has been demonstrated to be substantially equivalent to the predicate device.