July 30, 2018

Becton, Dickinson and Company
% Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, Minnesota 55313

Re: K172506
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: July 19, 2017
Received: August 18, 2017

Dear Mark Job:

This letter corrects our substantially equivalent letter of September 17th, 2017

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Geeta K.
Pamidimukkala -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K172506

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 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).

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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
	Fax Number	(801) 304-3963
	Date of Preparation:	September 14, 2017
Subject Device	Trade Name:	BD Cathena™ Safety IV Catheter
	Common Name:	Peripheral Intravascular or IV Catheter
	Regulation Number:	21 CFR §880.5200
	Regulation Name:	Intravascular Catheter
	Regulatory Class:	II
	Product Code:	FOZ
	Classification Panel:	General Hospital
Predicate Device (BD Insyte Autoguard BC)	Trade Name:	BD Insyte™ Autoguard™ BC
	510(k) Reference:	K110443
	Common Name:	Peripheral Intravascular or IV Catheter
	Regulation Number:	21 CFR §880.5200
	Regulation Name:	Intravascular Catheter
	Regulatory Class:	II
	Product Code:	FOZ
	Classification Panel:	General Hospital
Predicate Device (Introcan Safety 3)	Trade Name:	Introcan Safety® 3 Closed IV Catheter
	510(k) Reference:	K111236
	Common Name:	Peripheral Intravascular or IV Catheter
	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 Traditional 510(k) premarket notification is to notify CDRH of the introduction of the BD Cathena™ Safety IV Catheter device that has been demonstrated to be substantially equivalent to the predicate devices listed above.
Device Description	BD Cathena™ Safety IV Catheters are over-the-needle, intravascular 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 (24GA (0.7 mm)=Yellow, 22GA (0.9 mm)=Blue, 20GA (1.1 mm)=Pink, 18GA (1.3 mm)=Green, 16GA (1.7 mm)=Grey). These devices are not made with natural rubber latex.

Indications for Use

(21 CFR § 807.92(a)(5))

SUBJECT BD Cathena™ Safety IV Catheter	PREDICATE (K110443) BD Insyte™ Autoguard™ BC	PREDICATE (K111236) Introcan Safety® 3 Closed IV Catheter
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).	The BD Insyte Autoguard BC catheter is inserted into a patient's vascular system to sample blood, monitor blood pressure, or administer fluids.	Introcan Safety 3 Closed Intravascular Catheter is inserted into a patient's vascular system for short term use (less than 30 days) to sample blood, monitor blood pressure or administer fluids and blood intravascularly. The 18-22 gauge catheter may be used with power injectors at a maximum pressure of 300 psi with a luer lock connection only.

The subject and predicate devices have the same intended use. Both the subject and predicate devices are peripheral intravascular catheters intended to be inserted into the vascular system for short term use to sample blood, monitor blood pressure, or administer fluids intravenously. Patient population information was added to the subject device indication for use to clarify the patient population for which these devices can be used. The power injection pressure was also increased to 325psi to align with current power injector capabilities. The differences between the subject and predicate devices' indications for use do not change the intended use and do not raise different questions of safety and effectiveness.

Technological Characteristics

Technological characteristics of the subject and predicate devices are substantially equivalent with respect to the device design and materials. The subject BD Cathena™ Safety IV Catheter achieves its intended use based on the same technology and principles of operation as the predicate BD Insyte™ Autoguard™ BC and Introcan Safety® 3 Closed IV Catheter, respectively.

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

Attribute	SUBJECT BD Cathena™ Safety IV Catheter	PREDICATE (K110443) BD Insyte™ Autoguard™ BC	PREDICATE (K111236) Introcan Safety® 3 Closed IV Catheter
Classification	21 CFR §880.5200 Class II FOZ - Intravascular Catheter	21 CFR §880.5200 Class II FOZ - Intravascular Catheter	21 CFR §880.5200 Class II FOZ - Intravascular Catheter
Fundamental Scientific	Peripheral intravascular catheter designed with a	Peripheral intravascular catheter designed with an	Peripheral intravascular catheter designed with a

Technology	passive needlestick safety mechanism and a multi-use blood control septum. Incorporates BD Instaflash™ technology to assist with flashback visualization.	active needlestick safety mechanism and a one-time use blood control septum. Incorporates BD Instaflash™ technology to assist with flashback visualization.	passive needlestick safety mechanism and a multi-use blood control septum. Incorporates catheter flashback technology to assist with flashback visualization.
Primary Device Components / Materials	Safety Shield Polystyrene Grip / Needle Hub Polypropylene Needle Stainless Steel Catheter Adapter Polypropylene Catheter Tubing Polyurethane with radiopaque barium sulfate	Barrel Polypropylene or Polycarbonate Needle Hub Polycarbonate Needle Stainless Steel Catheter Adapter Polypropylene Catheter Tubing Polyurethane with radiopaque barium sulfate	Unknown
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 16G, 18 G, 20 G, 22 G, 24 G Catheter Lengths 0.75 IN, 1.00 IN, 1.16 IN, 1.77 IN, 1.88 IN	Catheter Diameters 18 G, 20 G, 22 G, 24 G Catheter Lengths 0.75 IN, 1.00 IN, 1.25 IN, 1.75 IN

Summary of Performance Tests

Performance tests completed on the subject device were those tests required to support a determination of substantial equivalence to the predicate devices. Design verification tests were performed based on the risk analysis. Results of these tests demonstrate that the BD Cathena™ Safety IV Catheter is substantially equivalent to the predicate devices. Design verification testing included the following:

- Package maintains integrity
- Needle cover does not fall off
- Force to remove needle cover
- Incremental force to decouple shielded needle from catheter adapter during safety activation
- System penetration force
- Needle to needle hub pull force
- Time to visualize flashback in flash chamber
- Catheter average drag force
- Force to break adhesion between catheter unit and needle (initial adhesion)
- Force to remove needle from catheter unit (average system drag)
- Force to prematurely decouple tip-shield from adapter
- Needle is not re-exposed upon application of compressive force
- Tensile force to defeat safety system

- No air leakage from device in a connected state at low pressure less than 30 psi
- Device burst pressure
- Catheter separation force
- Blood escape time
- Force to connect Luer to catheter adapter
- Time to visualize flashback in catheter adapter

Standards Compliance

- Gauging (ISO 594-1)
- Liquid leakage (ISO 594-1,-2, ISO 10555-1)
- Air leakage (ISO 594-1,-2)
- Separation force (ISO 594-1,-2)
- Stress cracking (ISO 594-2)
- Unscrewing torque (ISO 594-2)
- Ease of assembly (ISO 594-2)
- Resistance to overriding (ISO 594-2)
- Radio detectability (ISO 10555-1)
- Surface (ISO 10555-1, -5)
- Corrosion resistance (ISO 10555-1)
- Peak tensile force (ISO 10555-1)
- Flow rate (ISO 10555-1)
- Power injection (ISO 10555-1)
- Distal tip (ISO 105551-1)
- Needle point (ISO 10555-5)
- Strength of union between needle hub and needle tube (ISO 10555-5)
- Vent fitting (ISO 10555-1)
- Activation of the sharps injury protection feature (ISO 23908)
- Security of safe mode protection (ISO 23908)

In addition, biocompatibility testing was conducted on the BD Cathena™ Safety IV Catheters in accordance with *ISO 10993-1:2009, Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing Within a Risk Management Process*. Testing included cytotoxicity, sensitization, intracutaneous reactivity, acute systemic toxicity, subchronic toxicity (subacute toxicity), genotoxicity, implantation, and haemocompatibility. Additionally, material-mediated pyrogenicity was also performed.

Simulated clinical use testing was performed on the device, per FDA Guidance, *Applying Human Factors and Usability Engineering to Medical Devices* and IEC 62366-1:2015 *Medical devices - Part 1:Application of usability engineering to medical devices*.

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 devices.

Summary of Substantial Equivalence

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