December 18, 2020

Kimberly Geisler
Sr. Manager, Regulatory Affairs
9450 South State Street
Sandy, Utah 84070

Re: K201075
Trade/Device Name: BD Insyte™ Autoguard ™Shielded IV Catheter, BD Insyte™ Autoguard™ BC Shielded IV Catheter, BD Insyte™ Autoguard™ BC Pro Shielded IV Catheter
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: Class II
Product Code: FOZ, DYB
Dated: November 17, 2020
Received: November 19, 2020

Dear Kimberly Geisler:

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,

CAPT Alan M. Stevens
Acting 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)*
K201075

Device Name
BD Insyte™ Autoguard™ Shielded IV Catheter
BD Insyte™ Autoguard™ BC Shielded IV Catheter
BD Insyte™ Autoguard™ BC Pro Shielded IV Catheter

Indications for Use *(Describe)*

BD Insyte™ Autoguard™ Shielded 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 also be used to facilitate the placement of guidewires and other vascular access devices without pre-attached hubs.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 (0.9-1.3mm) devices are suitable for use with power injectors set to a maximum pressure of 300 psi (2068kPa).

BD Insyte™ Autoguard™ BC shielded 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. 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 Insyte™ Autoguard™ BC Pro shielded 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. 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).

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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Becton Dickinson Infusion Therapy Systems Inc.
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510(k) Summary: K201075

Submitter Information	Submitter Name:	Becton Dickinson Infusion Therapy Systems Inc.
	Submitter Address:	9450 South State Street Sandy, Utah 84070
	Contact Person:	Paul Holman Regulatory Affairs Specialist
	Email Address:	paul.holman@bd.com
	Phone Number:	(801) 565-2838
	Date of Preparation:	December 17, 2020
Subject Device	Trade Name:	BD Insyte™ Autoguard™ Shielded IV Catheter BD Insyte™ Autoguard™ BC Shielded IV Catheter BD Insyte™ Autoguard™ BC Pro Shielded IV Catheter
	510(k) Reference:	K201075
	Common Name:	Peripheral Intravascular or IV Catheter
	Regulation Number:	21 CFR §880.5200 (primary) 21 CFR §870.1340 (secondary for BD Insyte™ Autoguard™ Shielded IV Catheters only)
	Regulation Name:	Catheter, intravascular, therapeutic, short-term less than 30 days
	Regulatory Class:	II
	Product Code:	FOZ (primary) DYB (secondary for BD Insyte™ Autoguard™ Shielded IV Catheter only)
	Classification Panel:	General Hospital
Predicate Device	Trade Name:	BD Insyte™ Autoguard™ Shielded IV Catheter
	510(k) Reference:	K952861
	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 Device	Trade Name:	BD Insyte™ Autoguard™ BC Shielded IV Catheter
	510(k) Reference:	K110443
	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:	Introcan® Safety™ IV Catheter
	510(k) Reference:	K021094
	Common Name:	Peripheral Intravascular or IV Catheter/ Catheter Introducer
	Regulation Number:	21 CFR §880.5200 and §870.1340
	Regulation Name:	Catheter, intravascular, therapeutic, short-term less than 30 days Catheter Introducer
	Regulatory Class:	II
	Product Code:	FOZ/DYB
	Classification Panel:	Cardiovascular

Device Description

BD Insyte™ Autoguard™ Shielded IV Catheter

BD Insyte™ Autoguard™ shielded IV catheters are over-the-needle, intravascular (IV) catheters. These devices include a radiopaque BD Vialon™ catheter, needle, grip with button, flash chamber with vent plug, and barrel. The needle and catheter are protected by a needle cover.

The 24-20 GA (0.7-1.1 mm) 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. These devices incorporate BD Autoguard™ push-button shielding technology which is activated when the button is depressed. A spring mechanism retracts the needle and flash chamber into the barrel, fully encasing the needle and reducing the risk of accidental needlestick injury.

These devices are available with or without wings. The catheter hub and wings are color coded to indicate outside 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, 14 GA (2.1 mm) = Orange).

These devices facilitate the introduction of guidewires and other vascular access devices. The following labeled gauge sizes correspond to the listed inside diameter: 24 GA (0.40 mm), 22 GA (0.55 mm), 20 GA (0.7 mm), 18 GA (0.8 mm), 16 GA (1.2 mm), and 14 GA (1.6 mm).

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 Insyte™ Autoguard™ BC Shielded IV Catheter

BD Insyte™ Autoguard™ BC shielded IV catheters are over-the-needle, intravascular (IV) catheters with blood control technology. These devices include a radiopaque BD Vialon™ catheter, needle, grip with button, flash chamber with vent plug, and barrel. The needle and catheter are protected by a needle cover.

The blood control technology is designed to stop the flow of blood from the catheter hub until the initial Luer connection is made. Once the connection is made, fluids or blood can flow through the catheter hub in either direction. The blood control technology limits blood exposure to the device user.

The 24-20 GA (0.7-1.1 mm) 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.

These devices incorporate BD Autoguard™ push-button shielding technology which is activated when the button is depressed. A spring mechanism retracts the needle and flash chamber into the barrel, fully encasing the needle and reducing the risk of accidental needlestick injury.

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).

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 Insyte™ Autoguard™ BC Pro Shielded IV Catheter

BD Insyte™ Autoguard™ BC Pro shielded IV catheters are over-the-needle, intravascular (IV) catheters with blood control technology. These devices include a radiopaque BD Vialon™ catheter, needle, grip with button, flash chamber with vent plug, and barrel. The needle and catheter are protected by a needle cover.

The blood control technology is designed to stop the flow of blood from the catheter hub until the initial Luer connection is made. Once the connection is made, fluids or blood can flow through the catheter hub in either direction. The blood control technology limits blood exposure to the device user.

The 24-18 GA (0.7-1.1 mm) 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.

These devices incorporate BD Autoguard™ push-button shielding technology which is activated when the button is depressed. A spring mechanism retracts the needle and

	flash chamber into the barrel, fully encasing the needle and reducing the risk of accidental needlestick injury. 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). 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).
Indications for Use (21 CFR § 807.92(a)(5))	*<u>BD Insyte™ Autoguard™ Shielded IV Catheter</u>* *BD Insyte™ Autoguard™ shielded 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 also be used to facilitate the placement of guidewires and other vascular access devices without pre-attached hubs. 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).* *<u>BD Insyte™ Autoguard™ BC Shielded IV Catheter</u>* *BD Insyte™ Autoguard™ BC shielded 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. 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).* *<u>BD Insyte™ Autoguard™ BC Pro Shielded IV Catheter</u>* *BD Insyte™ Autoguard™ BC Pro shielded 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. 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).*
Technological Characteristics	Technological characteristics of the subject devices are substantially equivalent to the predicate devices. The subject BD Insyte™ Autoguard™ Shielded IV Catheter, BD Insyte™ Autoguard™ BC Shielded IV Catheter, and BD Insyte™ Autoguard™ BC Pro Shielded IV Catheter achieve their intended use based on the same technology and principles of operation as the predicate devices.

Comparisons of the subject and predicate devices technological characteristics are provided in the tables below.

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Subject / Predicate Device Comparison of Intended Use, Materials and Technological Characteristics

Subject Device: BD Insyte™ Autoguard™ Shielded IV Catheter

Attribute	SUBJECT BD Insyte™ Autoguard™ Shielded IV Catheter	PREDICATE BD Insyte™ Autoguard™ Shielded IV Catheter (K952861)	PREDICATE BBraun Introcan® Safety™ IV Catheter (K021094)	Substantial Equivalence
Classification	21 CFR §880.5200 21 CFR §870.1340 Class II FOZ - Intravascular Catheter (primary) DYB – Catheter Introducer (secondary)	21 CFR §880.5200 Class II FOZ - Intravascular Catheter	21 CFR §880.5200 21 CFR §870.1340 Class II FOZ – Intravascular Catheter DYB – Catheter Introducer	Same
Indications for Use	*BD Insyte™ Autoguard™ shielded 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 also be used to facilitate the placement of guidewires and other vascular access devices without pre-attached hubs. 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).*	*An intravascular catheter is intended to be inserted into the patient's vascular system for short term use to sample blood, monitor blood pressure, or administer fluids intravenously.*	*The BBraun Introcan® Safety IV Catheter is a passive anti-needle stick device to provide venous or arterial access for the infusion of fluids, drugs, and/or blood components, or to facilitate the placement of Vascular Access devices such as guidewires, indwelling central venous catheters, peripherally inserted central catheters, and midline catheters into the vascular system.*	Substantially Equivalent The subject device Indication for Use has been modified compared to the BD Insyte™ Autoguard™ Shielded IV Catheter predicate to clarify vascular insertion location, patient population, and power injection capabilities. These revisions serve to clarify product use and do not change the intended use of the product or introduce new features or functionality for vascular access; therefore, there are no new questions of safety or effectiveness. The subject device Indication for Use includes the facilitation of guidewire and other vascular access device placement which does not alter the overall intended use of the product with respect to the BBraun predicate device.

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Attribute	SUBJECT BD Insyte™ Autoguard™ Shielded IV Catheter	PREDICATE BD Insyte™ Autoguard™ Shielded IV Catheter (K952861)	PREDICATE BBraun Introcan® Safety™ IV Catheter (K021094)	Substantial Equivalence
Fundamental Scientific Technology	Single lumen with tapered tip peripheral intravascular catheter designed with an active needlestick safety mechanism. Incorporates BD Instaflash™ technology to assist with flashback visualization. Facilitates placement of guidewires and other vascular access devices.	Single lumen with tapered tip peripheral intravascular catheter designed with an active needlestick safety mechanism. Incorporates BD Instaflash™ technology to assist with flashback visualization.	Single lumen with tapered tip peripheral intravascular catheter designed with a passive needlestick safety* mechanism. Facilitates placement of guidewires and other vascular access devices.	Substantially Equivalent The subject and predicate BD Insyte™ Autoguard™ Safety IV Catheter active needlestick safety mechanisms are identical. *Passive and active needle safety mechanisms are well accepted technology for needlestick injury prevention in the clinical setting.
Primary Device Components / Materials	Needle Cover: Polypropylene Barrel: Polypropylene Grip: Polycarbonate Needle Hub: Polycarbonate Safety Activation Button: Polycarbonate Catheter Adapter: Polypropylene Catheter Wedge: Stainless Steel Needle: Stainless Steel Catheter Tubing: Polyurethane with radiopaque barium sulfate Lubricants: Silicone Spring: Stainless Steel Porous Flow Plug: Porous Polyethylene with Carboxymethyl Cellulose (CMC)	Needle Cover: Polypropylene Barrel: Polycarbonate Grip: Polycarbonate Needle Hub: Polycarbonate Safety Activation Button: Polycarbonate Catheter Adapter: Polypropylene Catheter Wedge: Stainless Steel Needle: Stainless Steel Catheter Tubing: Polyurethane with radiopaque barium sulfate Lubricants: Silicone Spring: Stainless Steel Porous Flow Plug: Porous Polyethylene with Carboxymethyl Cellulose (CMC)	Needle Cover: Polypropylene Catheter Tubing: Radiopaque Polyurethane (PUR) or Teflon (FEP) Catheter Adapter: Polypropylene Needle: Chrome-Nickel steel Needle Hub: ABS Catheter Wedge: Stainless Steel Safety Clip: Stainless steel Lubricants: Silicone	Substantially Equivalent The subject and predicate BD Insyte™ Autoguard™ Shielded IV Catheter materials are the same except the barrel material. The change in barrel material (non-patient contacting) does not alter or raise new questions of safety and efficacy. Subject device material differences compared to the predicate BBraun Introcan® Safety™ IV Catheter (K021094) are non-significant relative to the catheter introducer indication. Materials contacting and interfacing with the guidewire or other vascular access device include catheter tubing, catheter adapter and catheter wedge. These materials are substantially equivalent to the predicate BBraun Introcan® Safety™ IV Catheter.

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Attribute	SUBJECT BD Insyte™ Autoguard™ Shielded IV Catheter	PREDICATE BD Insyte™ Autoguard™ Shielded IV Catheter (K952861)	PREDICATE BBraun Introcan® Safety™ IV Catheter (K021094)	Substantial Equivalence
Catheter Dimensions	Catheter Diameters 14 GA, 16 GA, 18 GA, 20 GA, 22 GA, 24 GA Catheter Lengths 0.56 IN, 0.75 IN, 1.00 IN, 1.16 IN, 1.75 IN, 1.77 IN, 1.88 IN Catheter ID 0.0190 IN – 0.0705 IN	Catheter Diameters 14 GA, 16 GA, 18 GA, 20 GA, 22 GA, 24 GA Catheter Lengths 0.56 IN, 0.75 IN, 1.00 IN, 1.16 IN, 1.75 IN, 1.77 IN, 1.88 IN Catheter ID 0.0190 IN – 0.0705 IN	Catheter Diameters 14 GA, 16 GA, 18 GA, 20 GA, 22 GA, 24 GA Catheter Lengths 0.55 IN, 0.75 IN, 1.00 IN, 1.25 IN, 1.75 IN, 2.00 IN, 2.50 IN Catheter ID 0.018 IN – 0.064 IN	Substantially Equivalent The subject device and predicate BD Insyte™ Autoguard™ Shielded IV Catheter dimensions are identical. The subject and predicate devices are available in winged/non-winged configurations with similar gauges, lengths, and sizes. Catheter ID dimensions allow passage of vascular access devices, including a standard appropriately sized guidewire or catheter through the lumen of the subject/predicate devices.
Performance	Power Injection 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) Flashback Chamber / Technology Yes Safety Design Yes Radiopaque Yes Must allow passage of appropriate size guide wire or catheter Yes	Power Injection 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) Flashback Chamber / Technology Yes Safety Design Yes Radiopaque Yes	Power Injection The 22-18 GA power injection max pressure 300 psi (2068 kPa) Flashback Chamber / Technology Yes Safety Design Yes Radiopaque Yes Must allow passage of appropriate size guide wire or catheter Yes	Same

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Attribute	SUBJECT BD Insyte™ Autoguard™ Shielded IV Catheter	PREDICATE BD Insyte™ Autoguard™ Shielded IV Catheter (K952861)	PREDICATE BBraun Introcan® Safety™ IV Catheter (K021094)	Substantial Equivalence
Standards Compliance	ISO 594-1 ISO 594-2 ISO 10555-1 ISO 10555-5 ISO 23908 ISO 11070	ISO 594-1 ISO 594-2 ISO 10555-1 ISO 10555-5 ISO 23908	Unknown	Substantially Equivalent The subject device was evaluated to current FDA recognized and industry consensus standards applicable to the device classification and FDA product codes.

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Subject / Predicate Device Comparison of Intended Use, Materials and Technological Characteristics

Subject Device: BD Insyte™ Autoguard™ BC Shielded IV Catheter

Subject Device: BD Insyte™ Autoguard™ BC Pro Shielded IV Catheter

Attribute	SUBJECT BD Insyte™ Autoguard™ BC Shielded IV Catheter BD Insyte™ Autoguard™ BC Pro Shielded IV Catheter	PREDICATE BD Insyte™ Autoguard™ BC Shielded IV Catheter (K110443)	Substantial Equivalence
Classification	21 CFR §880.5200 Class II FOZ – Intravascular Catheter	21 CFR §880.5200 Class II FOZ – Intravascular Catheter	Same
Indications for Use	**BD Insyte™ Autoguard™ BC Shielded IV Catheter:** BD Insyte™ Autoguard™ BC shielded 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. 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 Insyte™ Autoguard™ BC Pro Shielded IV Catheter:** BD Insyte™ Autoguard™ BC Pro shielded 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. 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).	The BD Insyte™ Autoguard™ BC catheter is inserted into a patient's vascular system to sample blood, monitor blood pressure, or administer fluids.	Substantially Equivalent The subject device Indication for Use has been modified to clarify vascular insertion location, duration of use, patient population, power injection capabilities and to align with current industry standards and FDA expectations These revisions serve to clarify product use and do not change the intended use of the product or introduce new features or functionality; therefore, there are no new questions of safety or effectiveness when considering a claim of substantial equivalence.

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Attribute	SUBJECT BD Insyte™ Autoguard™ BC Shielded IV Catheter BD Insyte™ Autoguard™ BC Pro Shielded IV Catheter	PREDICATE BD Insyte™ Autoguard™ BC Shielded IV Catheter (K110443)	Substantial Equivalence
Fundamental Scientific Technology	Peripheral intravascular catheter designed with an active needlestick safety mechanism and a one-time use blood control septum. Incorporates BD Instaflash™ technology to assist with flashback visualization.	Peripheral intravascular catheter designed with an active needlestick safety mechanism and a one-time use blood control septum. Incorporates BD Instaflash™ technology to assist with flashback visualization.	Substantially Equivalent There are no significant design differences between the subject devices and BD Insyte™ Autoguard™ BC Shielded IV Catheter predicate.
Primary Device Components / Materials	Needle Cover: Polypropylene Barrel: Polypropylene Grip: Polycarbonate Needle Hub: Polycarbonate Safety Activation Button: Polycarbonate Catheter Adapter: Polypropylene Catheter Wedge: Stainless Steel Needle: Stainless Steel Catheter Tubing: Polyurethane with radiopaque barium sulfate Lubricants: Silicone Spring: Stainless Steel Porous Flow Plug: Porous Polyethylene with Carboxymethyl Cellulose (CMC) Septum: Silicone Septum Actuator: Polypropylene	Needle Cover: Polypropylene Barrel: Polycarbonate Grip: Polycarbonate Needle Hub: Polycarbonate Safety Activation Button: Polycarbonate Catheter Adapter: Polypropylene Catheter Wedge: Stainless Steel Needle: Stainless Steel Catheter Tubing: Polyurethane with radiopaque barium sulfate Lubricants: Silicone Spring: Stainless Steel Porous Flow Plug: Porous Polyethylene with Carboxymethyl Cellulose (CMC) Septum: Silicone Septum Actuator: Polypropylene	Substantially Equivalent The subject and predicate device materials are the same except for the barrel change from polycarbonate to polypropylene (non-patient contacting). The change in barrel material does not alter or raise new questions of safety and efficacy; therefore, it is substantially equivalent.
Catheter Dimensions	Catheter Diameters 16 GA, 18 GA, 20 GA, 22 GA, 24 GA Catheter Lengths 0.75 IN, 1.00 IN, 1.16 IN, 1.25IN (BD Insyte™ Autoguard™ BC Pro Shielded IV Catheter ONLY) 1.77 IN, 1.88 IN	Catheter Diameters 16 GA, 18 GA, 20 GA, 22 GA, 24 GA Catheter Lengths 0.75 IN, 1.00 IN, 1.16 IN, 1.77 IN, 1.88 IN	Substantially Equivalent New 1.25 IN configuration was introduced for BD Insyte™ Autoguard™ BC Pro Shielded IV Catheter ONLY. This 1.25 IN length falls within the range of the existing predicate, the new length does not raise any new or different questions of safety or

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Attribute	SUBJECT BD Insyte™ Autoguard™ BC Shielded IV Catheter BD Insyte™ Autoguard™ BC Pro Shielded IV Catheter	PREDICATE BD Insyte™ Autoguard™ BC Shielded IV Catheter (K110443)	Substantial Equivalence
			effectiveness as demonstrated through design verification testing; therefore, it is substantially equivalent.
Performance	Power Injection 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) Flashback Chamber / Technology Yes Blood Control Mechanism Yes Needle Safety Design Yes Radiopaque Yes	Power Injection 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) Flashback Chamber / Technology Yes Blood Control Mechanism Yes Needle Safety Design Yes Radiopaque Yes	Same
Standards Compliance	ISO 594-1 ISO 594-2 ISO 10555-1 ISO 10555-5 ISO 23908	ISO 594-1 ISO 594-2 ISO 10555-1 ISO 10555-5 ISO 23908	Same

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Summary of Performance Tests	A risk analysis per ISO 14971:2007 "Medical Devices-Application of risk management to medical devices" was conducted to assess the impact of the proposed modifications to the predicate devices. Performance tests completed on the subject devices were limited to those tests required to support a determination of substantial equivalence to the predicate devices. There are no leveraged tests from the predicate devices. • ISO 10555-1: 2013 + A1:2017 Sterile, single-use intravascular catheters - Part 1: General requirements • ISO 10555-5 :2013 Intravascular catheters – Sterile and single-use catheters Part 5: Over-needle peripheral catheters • ISO 594-1:1986 Conical Fitting with a 6% (Luer) Taper for Syringes, Needless and certain other medical equipment – Part 1: General Requirements • ISO 594-2 :1998 Conical Fittings with a 6% (Luer) Taper for syringes, needless and certain other medical equipment – Part 2: Lock Fittings • ISO 23908:2011 Sharps injury protection — Requirements and test methods — Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling • ISO 11070:2014 "Sterile single-use intravascular introducer, dilators and guidewires 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. The following testing was undertaken to support the biocompatibility of the subject devices: • ISO 10993-3:2014 Biological evaluation of medical devices Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity • ISO 10993-4:2017 Biological evaluation of medical devices Part 4: Selection of tests for interactions with blood • ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity • ISO 10993-6:2016 Biological evaluation of medical devices Part 6: Tests for local effects after implantation • ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization • ISO 10993-11:2017 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity

	• ISO 10993-12:2012 Biological evaluation of medical devices – Part 12: Sample preparation and reference materials • Particulate Matter per USP <788> Sterilization and Packaging validation • ISO 11135-1:2014 Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices • ISO 11607-1:2006+AI:2014 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems • ISO 11607-2:2006 Packaging for terminally sterilized medical devices Part 2: Validation requirements for forming, sealing and assembly processes • ISO 10993-7:2008 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
Summary of Substantial Equivalence	Based on the indications for use, technological characteristics, and results of performance testing, the subject BD Insyte™ Autoguard™ Shielded IV Catheter, BD Insyte™ Autoguard™ BC Shielded IV Catheter, and BD Insyte™ Autoguard™ BC Pro Shielded IV Catheter have been demonstrated to be substantially equivalent to the legally marketed predicate devices.