



June 27, 2025

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

Re: K251654

Trade/Device Name: BD Insyte™ Autoguard™ Shielded IV Catheter, BD Insyte™ Autoguard™ BC  
Shielded IV Catheter and 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

Dated: May 29, 2025

Received: May 30, 2025

Dear Laura Castelnoble:

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**PORSCHE P. BENNETT -S**

Porsche Bennett

*For* 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

510(k) Number (if known)

K251654

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 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 also be used to facilitate the placement of guidewires and other vascular access devices such as catheters without pre-attached hubs. 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. 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 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. The 22-18GA (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 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. 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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**510(k) Summary (21 CFR §807.92)**

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

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<b>Submitter Information</b>	Submitter Name:	Becton Dickinson Infusion Therapy Systems Inc.
	Submitter Address:	9450 South State Street, Sandy, Utah 84070
	Contact Person:	Laura Castelnoble, Staff Regulatory Affairs Specialist
	Email Address:	Laura.Castelnoble@bd.com
	Phone Number:	801-522-5000
	Date of Preparation:	May 29, 2025
<b>Subject Device</b>	Trade Name:	BD Insyte™ Autoguard™ Shielded IV Catheter BD Insyte™ Autoguard™ BC Shielded IV Catheter BD Insyte™ Autoguard™ BC Pro Shielded IV Catheter
	Common Name:	Peripheral Intravascular or IV Catheter/ Catheter Introducer
	Regulation Number:	21 CFR 880.5200 21 CFR 870.1340 (secondary for BD Insyte™ Autoguard™ Shielded IV Catheter only)
	Regulation Name:	Catheter, intravascular, therapeutic, short-term less than 30 days/ Catheter Introducer
	Regulatory Class:	II
	Product Code:	FOZ (Primary); DYB (Secondary)
	Classification Panel:	General Hospital
	<b>Predicate Device</b>	Trade Name:
510(k) Reference:		K201075
Common Name:		Peripheral Intravascular or IV Catheter/Catheter Introducer
Regulation Number:		21 CFR 880.5200 21 CFR 870.1340 (secondary for BD Insyte™ Autoguard™ Shielded IV Catheter only)
Regulation Name:		Catheter, intravascular, therapeutic, short-term less than 30 days / Catheter Introducer
Regulatory Class:		II
Product Code:		FOZ (Primary); DYB (Secondary)
Classification Panel:		General Hospital

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**Reason for Submission**

The purpose of this submission is to notify the FDA of the following:

- Creation of new performance specifications for Blood Fill Time (Blood Sampling), Frequency Response (Blood Pressure Monitoring), Catheter Kink Resistance (Blood Pressure Monitoring) to support the current indications for use
- Revised IFU to clarify potential complications, warnings, precautions and instructions related to the blood pressure monitoring and arterial use, ensure compliance with EUMDR and other minor clerical changes.

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**Device Description**

**BD Insyte™ Autoguard™ Shielded IV Catheter**

BD Insyte™ Autoguard™ Shielded IV Catheter is an over-the-needle, intravascular (IV) catheter. This device includes a radiopaque BD Vialon™ Catheter Material, a needle, a grip with button, a flash chamber with vent plug, and a 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.

BD Insyte™ Autoguard™ Shielded IV Catheter incorporates 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.

BD Insyte™ Autoguard™ Shielded IV Catheter is available with or without wings. The catheter hub and wings 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, 16 GA (1.7 mm) = Grey, 14 GA (2.1 mm) = Orange).

BD Insyte™ Autoguard™ Shielded IV Catheter facilitates the introduction of guidewires and other vascular access devices. The following labeled gauge sizes correspond to the following inside diameter (ID): 24 GA (0.40 mm ID), 22 GA (0.55 mm ID), 20 GA (0.7 mm ID), 18 GA (0.8 mm ID), 16 GA (1.2 mm ID), and 14 GA (1.6 mm ID).

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 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 Catheter is an over-the-needle, intravascular (IV) catheter with blood control technology. This device includes a radiopaque BD Vialon™ Catheter Material, a needle, a grip with button, a flash chamber with vent plug, and a barrel. The needle and catheter are protected by a needle cover.

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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 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.

BD Insyte™ Autoguard™ BC Shielded IV Catheter 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.

BD Insyte™ Autoguard™ BC Shielded 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).

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 Catheter is an over-the-needle, intravascular (IV) catheter with blood control technology. This device includes a radiopaque BD Vialon™ Catheter Material, a needle, a grip with button, a flash chamber with vent plug, and a 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 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.

BD Insyte™ Autoguard™ BC Pro Shielded IV Catheter 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.

BD Insyte™ Autoguard™ BC Pro Shielded 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).

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).

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**Indications for Use**  
**(21 CFR § 807.92(a)(5))**

**BD Insyte™ Autoguard™ Shielded IV Catheter**

BD Insyte™ Autoguard™ Shielded 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 also be used to facilitate the placement of guidewires and other vascular access devices such as catheters without pre-attached hubs. 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. 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 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. The 22-18GA (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 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. 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).

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**Technological Characteristics**

Technological characteristics of the subject device are substantially equivalent to the predicate device. The subject device 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 device.

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

**Note:** Highlighted **blue text** indicates differences from the predicate device

Attribute	SUBJECT BD Insyte™ Autoguard™, Insyte™ Autoguard™ BC and Insyte™ Autoguard™ BC Pro Shielded IV Catheter	PREDICATE (K201075) BD Insyte™ Autoguard™, Insyte™ Autoguard™ BC and Insyte™ Autoguard™ BC Pro Shielded IV Catheter	Substantially Equivalent?
Classification	21 CFR 880.5200 21 CFR 870.1340 (BD Insyte™ Autoguard™ Shielded IV Catheter ONLY) Class II FOZ - Intravascular Catheter DYB – Catheter Introducer (BD Insyte™ Autoguard™ Shielded IV Catheter ONLY)	21 CFR 880.5200 21 CFR 870.1340 (BD Insyte™ Autoguard™ Shielded IV Catheter ONLY) Class II FOZ - Intravascular Catheter DYB – Catheter Introducer (BD Insyte™ Autoguard™ Shielded IV Catheter ONLY)	Same as the predicate.
Indications for Use – Single Port Configurations	<p><u><i>BD Insyte™ Autoguard™ Shielded IV Catheter</i></u>            BD Insyte™ Autoguard™            Shielded 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 also be used to facilitate the            placement of guidewires and            other vascular access devices            such as catheters without pre-            attached hubs. 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. 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).</p> <p><u><i>BD Insyte™ Autoguard™ BC Shielded IV Catheter</i></u>            BD Insyte™ Autoguard™ BC            Shielded 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</p>	<p><u><i>BD Insyte™ Autoguard™ Shielded IV Catheter</i></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).</p> <p><u><i>BD Insyte™ Autoguard™ BC Shielded IV Catheter</i></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</p>	<p>Yes</p> <p>Same as predicate with            minor wording changes as            indicated with no change            to the substance, meaning            or scope.</p>

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	<p>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)</p> <p><u><i>BD Insyte™ Autoguard™ BC Pro Shielded IV Catheter</i></u></p> <p>BD Insyte™ Autoguard™ BC Pro Shielded 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. 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).</p>	<p>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).</p> <p><u><i>BD Insyte™ Autoguard™ BC Pro Shielded IV Catheter</i></u></p> <p>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).</p>	
<p><b>Fundamental Scientific Technology</b></p>	<p><u><i>BD Insyte™ Autoguard™ Shielded IV Catheter</i></u></p> <p>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.</p> <p><u><i>BD Insyte™ Autoguard™ BC / BD Insyte™ Autoguard™ BC Pro</i></u></p> <p>Peripheral intravascular catheter designed with an active needlestick safety mechanism and a one-time use blood control septum (offered with or without</p>	<p><u><i>BD Insyte™ Autoguard™ Shielded IV Catheter</i></u></p> <p>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.</p> <p><u><i>BD Insyte™ Autoguard™ BC / BD Insyte™ Autoguard™ BC Pro</i></u></p> <p>Peripheral intravascular catheter designed with an active needlestick safety mechanism and a one-time use blood control septum (offered with or without this technology). Incorporates BD</p>	<p>Yes Same as predicate</p>

	<p>this technology). Incorporates BD Instaflash™ technology to assist with flashback visualization.</p>	<p>Instaflash™ technology to assist with flashback visualization.</p>	
<p><b>Catheter Dimensions</b></p>	<p><u>BD Insyte™ Autoguard™</u>          Catheter Diameters - 14GA, 16 GA, 18 GA, 20 GA, 22GA, 24 GA          Catheter Lengths - 0.56 IN, 0.75 IN, 1.00 IN, 1.16 IN, 1.75IN, 1.77IN, 1.88IN</p> <p><u>BD Insyte™ Autoguard™ BC</u>          Catheter Diameters - 16 GA, 18 GA, 20 GA, 22GA, 24 GA          Catheter Lengths – 0.75IN, 1.00IN, 1.16IN, 1.77IN, 1.88IN</p> <p><u>BD Insyte™ Autoguard™ BC Pro</u>          Catheter Diameters - 16 GA, 18 GA, 20 GA, 22GA, 24 GA          Catheter Lengths – 0.75IN, 1.00IN, 1.16 IN, 1.25IN, 1.77IN, 1.88IN</p>	<p><u>BD Insyte™ Autoguard™</u>          Catheter Diameters - 14GA, 16 GA, 18 GA, 20 GA, 22GA, 24 GA          Catheter Lengths - 0.56 IN, 0.75 IN, 1.00 IN, 1.16 IN, 1.75IN, 1.77IN, 1.88IN</p> <p><u>BD Insyte™ Autoguard™ BC</u>          Catheter Diameters - 16 GA, 18 GA, 20 GA, 22GA, 24 GA          Catheter Lengths – 0.75IN, 1.00IN, 1.16IN, 1.77IN, 1.88IN</p> <p><u>BD Insyte™ Autoguard™ BC Pro</u>          Catheter Diameters - 16 GA, 18 GA, 20 GA, 22GA, 24 GA          Catheter Lengths – 0.75IN, 1.00IN, 1.16 IN, 1.25IN, 1.77IN, 1.88IN</p>	<p>Yes          Same as predicate</p>
<p><b>Product Configurations</b></p>	<ul style="list-style-type: none"> <li>• 14 – 24GA (Insyte Autoguard ONLY)</li> <li>• 14 – 24GA Winged (Insyte Autoguard ONLY)</li> <li>• 16 – 24GA 16 – 24GA Winged</li> </ul>	<ul style="list-style-type: none"> <li>• 14 – 24GA (Insyte Autoguard ONLY)</li> <li>• 14 – 24GA Winged (Insyte Autoguard ONLY)</li> <li>• 16 – 24GA 16 – 24GA Winged</li> </ul>	<p>Yes          Same as predicate</p>

<b>Sterilization Modality</b>	• Ethylene Oxide	• Ethylene Oxide	Yes Same as predicate
<b>Device Materials</b>			
<b>Needle Cover</b>	Polypropylene	Polypropylene	Same as predicate
<b>Needle</b>	Stainless Steel	Stainless Steel	Same as predicate
<b>Catheter Tubing</b>	Polyurethane with barium sulfate	Polyurethane with barium sulfate	Same as predicate
<b>Catheter Adapter</b>	Polypropylene + Colorant 24GA (Yellow) 22GA (Blue) 20GA (Pink) <b>18GA (Green)</b> 16GA (Gray) 14GA (Orange) – Insyte Autoguard ONLY	Polypropylene + Colorant 24GA (Yellow) 22GA (Blue) 20GA (Pink) 18GA (Green) 16GA (Gray) 14GA (Orange) – Insyte Autoguard ONLY	Same as predicate. A new catheter adapter green colorant sub-supplier was qualified. <b>Previous Supplier:</b> Green Pigment - Lionel Green 6Y-501, CAS #14302-13-7 <b>Current Supplier:</b> Green Pigment – 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.
<b>Catheter Wedge</b>	Stainless Steel	Stainless Steel	Same as predicate
<b>Safety Activation Button</b>	Polycarbonate +White Colorant	Polycarbonate +White Colorant	Same as predicate
<b>Grip</b>	Polycarbonate	Polycarbonate	Same as predicate
<b>Needle Hub</b>	Polycarbonate	Polycarbonate	Same as predicate
<b>Barrel</b>	Polypropylene	Polypropylene	Same as predicate
<b>Lubricants</b>	Silicone	Silicone	Same as predicate
<b>Porous Flow Plug (Vent Plug)</b>	Porous Polyethylene with Carboxymethyl Cellulose (CMC)	Porous Polyethylene with Carboxymethyl Cellulose (CMC)	Same as predicate
<b>Spring</b>	Stainless Steel	Stainless Steel	Same as predicate

<b>Septum        (Insyte™        Autoguard™ BC        and Insyte™        Autoguard™ BC        Pro ONLY)</b>	Silicone	Silicone	Same as predicate
<b>Septum        Actuator        (Insyte™        Autoguard™ BC        and Insyte™        Autoguard™ BC        Pro ONLY)</b>	Polypropylene	Polypropylene	Same as predicate
<b>Comparison        of Subject /        Predicate        Device        Primary        Device        Component        Materials</b>	Top Web: Medical Grade Paper with heat seal coating  Bottom Web: Nylon / Polyethylene substrate polymer layers	Top Web: Medical Grade Paper with heat seal coating  Bottom Web: Nylon / Polyethylene substrate polymer layers	Both subject and predicate materials consist of packaging paper material which includes heat-sealing coating designed for medical applications. The difference in thickness does not impact sterile barrier or device performance. The results of performance testing demonstrate that the subject device performs as intended

**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:

BD Internal Requirements:

- Frequency Response Testing,
- Kink Resistance Testing,
- Blood Fill Time Testing,
- Catheter Separation Force,

Compliance with Standards Testing:

**Luer Testing**

ISO 80369-7 Second edition 2021-05; Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications

**Packaging Testing**

ISO 11607-1 Second edition 2019-02 - Packaging for terminally sterilized medical devices - Part 1: Requirements for materials sterile barrier systems and packaging systems

- ASTM F2096-11 (Reapproved 2019) - Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)
- ASTM F88/F88M-15 - Standard Test Method for Seal Strength of Flexible Barrier Materials

**Biocompatibility**

ISO 10993-1:2018 Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process

- ISO 10993-5:2009 Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity

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.

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**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, K201075.

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