



October 8, 2025

Becton Dickinson Infusion Therapy Systems Inc.  
Sunny Patel  
Senior Regulatory Affairs Specialist  
9450 South State Street  
Sandy, Utah 84070

Re: K251422

Trade/Device Name: BD Saf-T-Intima™ Subcutaneous Catheter System  
Regulation Number: 21 CFR 880.5200  
Regulation Name: Intravascular Catheter  
Regulatory Class: Class II  
Product Code: FOZ  
Dated: September 5, 2025  
Received: September 5, 2025

Dear Sunny Patel:

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,

**David Wolloscheck -S**

David Wolloscheck, Ph.D.

Assistant Director

DHT3C: Division of Drug Delivery and  
General Hospital Devices, and  
Human Factors

OHT3: Office of Gastrorenal, ObGyn,  
General Hospital, and Urology Devices  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K251422

Device Name

BD Saf-T-Intima™ Subcutaneous Catheter System

Indications for Use (Describe)

BD Saf-T-Intima™ Subcutaneous Catheter System is intended to be inserted into a patient's subcutaneous tissue for short term use for the administration of fluids and medications. This device is also intended to be inserted into a patient's peripheral venous system for short term use to administer fluids or sample blood. This device may be used for any patient population with consideration given to adequacy of subcutaneous tissue or vascular anatomy, procedure being performed, fluids being infused, and duration of therapy.

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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## K251422 510(k) Summary (21 CFR §807.92)

### BD Saf-T-Intima™ Subcutaneous Catheter System

<b>Submitter Information</b>	Submitter Name:	Becton Dickinson Infusion Therapy Systems Inc.
	Submitter Address:	9450 South State Street, Sandy, Utah 84070
	Contact Person:	Sunny Patel, Senior Regulatory Affairs Specialist
	Email Address:	<a href="mailto:sunny.patel@bd.com">sunny.patel@bd.com</a>
	Phone Number:	801-522-5132
	Date of Preparation:	October 03, 2025
<b>Subject Device</b>	Trade Name:	BD Saf-T-Intima™ Subcutaneous Catheter System
	Common Name:	Short-term less than 30 days intravascular, therapeutic catheter
	Regulation Number:	21 CFR 880.5200
	Regulation Name:	Intravascular catheter
	Regulatory Class:	II
	Product Code:	FOZ
	Classification Panel:	General Hospital
<b>Predicate Device</b>	Trade Name:	BD Saf-T-Intima™ Intravascular Catheter
	510(k) Reference:	K013800
	Common Name:	Short-term less than 30 days intravascular, therapeutic catheter
	Regulation Number:	21 CFR 880.5200
	Regulation Name:	Intravascular catheter
	Regulatory Class:	II
	Product Code:	FOZ
	Classification Panel:	General Hospital
<b>Device Description</b>	<p>BD Saf-T-Intima™ Subcutaneous Catheter System is an over-the-needle subcutaneous and intravenous (IV) catheter. This device includes a radiopaque BD Vialon™ Catheter Material, a needle attached to a wire stylet, wings for insertion assistance and catheter securement, integrated extension tubing, a clamp, a single or dual port, a BD® PRN Adapter, vent plug (dual port only), and a needle shield. The needle and catheter are protected by a needle cover.</p> <p>BD Saf-T-Intima™ Subcutaneous Catheter System is designed to keep blood contained within the device throughout the insertion process. The needle is passively protected when it is removed, reducing the risk of accidental needlestick injury. Both the wings and single port or dual port are color coded to indicate catheter gauge size (24 GA (0.7 mm) = Yellow, 22 GA (0.9 mm) = Blue).</p>	

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<b>Indications for Use</b> <b>(21 CFR § 807.92(a)(5))</b>	<b>BD Saf-T-Intima™ Subcutaneous Catheter System</b>  BD Saf-T-Intima™ Subcutaneous Catheter System is intended to be inserted into a patient’s subcutaneous tissue for short term use for the administration of fluids and medications. This device is also intended to be inserted into a patient’s peripheral venous system for short term use to administer fluids or sample blood. This device may be used for any patient population with consideration given to adequacy of subcutaneous tissue or vascular anatomy, procedure being performed, fluids being infused, and duration of therapy.
<b>Technological Characteristics</b>	<p>Technological characteristics of the subject and predicate devices are the same. The subject and predicate devices are a single-lumen winged polyurethane IV or subcutaneous use catheter with an integrated extension set incorporating either a single port (straight connection with PRN adapter) or dual port (Y connection with PRN adapter and vent plug). The subject and predicate devices’ intended use is based on the same technology and principles of operation. Therefore, the subject device is considered substantially equivalent to the predicate device, BD Saf-T-Intima™ Intravascular Catheter, K013800. Any modifications made to the subject device have been determined to have no impact to the safety or performance of the device. Any new or different risks have been documented and reduced as far as practicable following risk management practices outlined in ISO 14971.</p> <p>A comparison of the subject and predicate device technological characteristics is provided in the table below.</p>

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**Table 1-1. Comparison of Subject / Predicate Device**

NOTE: Highlighted **blue text** indicates differences between the subject and predicate device.

Attribute	SUBJECT (K251422) BD Saf-T-Intima™ Subcutaneous Catheter System	PREDICATE (K013800) BD Saf-T-Intima™ Intravascular Catheter	Substantially Equivalent?
Trade Name	BD Saf-T-Intima™ <b>Subcutaneous Catheter System</b>	BD Saf-T-Intima™ Intravascular Catheter	Yes Minor descriptive changes.
Common Name	Peripheral Intravascular Catheter or IV Catheter	Peripheral Intravascular Catheter or IV Catheter	Yes
Regulation Number	21 CFR §880.5200	21 CFR §880.5200	Yes
Regulatory Name	Intravascular Catheter	Intravascular Catheter	Yes
Regulatory Class	II	II	Yes
Product Code	FOZ	FOZ	Yes
Classification Panel	General Hospital	General Hospital	Yes
Intended Use	<b>BD Saf-T-Intima™ Subcutaneous Catheter System</b> is intended for short term use to sample blood and administer fluids.	BD Saf-T-Intima™ Safety System is intended for short term use to sample blood and administer fluids.	Yes Minor descriptive changes.
Indications for Use	<b>Single Port / Dual Port: BD Saf-T-Intima™ Subcutaneous Catheter System is intended to be inserted into a patient's subcutaneous tissue for short term use for the administration of fluids and medications. This device is also intended to be inserted into a patient's peripheral venous system for short term use to administer fluids or sample blood. This device may be used for any patient population with consideration given to adequacy of subcutaneous tissue or</b>	An intravascular catheter is a device that consists of a slender tube and any necessary connecting fittings and that is inserted into the patient's vascular system for short term use (less than 30 days) to sample blood, monitor blood pressure, or administer fluids intravenously. These catheters may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness of procedure.	Yes  The Indications for Use for the BD Saf-T-Intima™ Subcutaneous Catheter System is being narrowed to sample blood or administer fluids (Intravenous use ONLY). The indications for use are also expanded to include anatomical site-specific use for subcutaneous access.  These modifications are intended to provide clarity for device use

Attribute	SUBJECT BD Saf-T-Intima™ Subcutaneous Catheter System	PREDICATE (K013800) BD Saf-T-Intima™ Intravascular Catheter	Substantially Equivalent?
	vascular anatomy, <b>procedure being performed, fluids being infused, and duration of therapy.</b>		with no change to patient population or use duration. The proposed Indications for Use fall within the general intended use and does not raise any new or different questions of safety or effectiveness, nor impact the performance of the device
<b>Fundamental Scientific Technology</b>	A single-winged, polyurethane IV catheter with an integrated extension set incorporating either a single port or Y (dual)-port injection site.	A single-winged, polyurethane IV catheter with an integrated extension set incorporating either a single port or Y (dual)-port injection site.	Yes
<b>ISO 10993 Biocompatibility Contact Type and Duration</b>	<u>Body contact:</u> Externally communicating device <u>Contact:</u> Circulating blood <u>Contact duration:</u> Limited (A) to Prolonged (B) (≤ 24 hrs to 30 days)	<u>Body contact:</u> Externally communicating device <u>Contact:</u> Circulating blood <u>Contact duration:</u> Limited (A) to Prolonged (B) (≤ 24 hrs to 30 days)	Yes
<b>Catheter Dimensions</b>	<u>Catheter Diameters</u> 22 GA, 24 GA <u>Catheter Lengths</u> 0.75 IN	<u>Catheter Diameters</u> 18 GA, 20 GA, 22 GA, 24 GA <u>Catheter Lengths</u> 0.75 IN, 1.00 IN	Yes
<b>Product Configurations</b>	<ul style="list-style-type: none"> <li>• Single Port (Straight connection with PRN adapter)</li> <li>• Dual Port (Y connection with PRN adapter and vent plug)</li> </ul>	<ul style="list-style-type: none"> <li>• Straight connection with PRN adapter</li> <li>• Y connection (dual port) with PRN adapter and vent plug</li> </ul>	Yes

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The BD Saf-T-Intima™ Subcutaneous Catheter System is considered substantially equivalent to the predicate device, BD Saf-T-Intima™ Intravascular Catheter (K013800), based on a comprehensive comparison of key attributes. The differences in substantial equivalence between the BD Saf-T-Intima™ Subcutaneous Catheter System and the predicate BD Saf-T-Intima™ Intravascular Catheter primarily involve the indications for use. The subject device expands its indications to include subcutaneous access and narrows its intravenous use to administer fluids or sample blood only, whereas the predicate device includes blood pressure monitoring. Additionally, the subject device offers fewer catheter sizes—only 22 GA and 24 GA with a 0.75-inch length, compared to the predicate’s range of 18GA, 20GA, 22GA, 24GA and lengths of 0.75 and 1.00 inches. These differences do not raise new questions of safety or effectiveness and are well supported by data demonstrating substantial equivalence.

**Table 1-2. Comparison of Subject / Predicate Device Material**

**NOTE:** Highlighted **blue text** indicates differences between the subject and predicate device.

Attribute	Component	SUBJECT BD Saf-T-Intima™ Subcutaneous Catheter System	PREDICATE (K013800) BD Saf-T-Intima™ Intravascular Catheter	Substantially Equivalent?
	Needle Cover	Tenite Propionate	Tenite Propionate	Yes
	Needle	Stainless Steel	Stainless Steel	Yes
	Catheter Tubing	Polyurethane (BD Vialon™)	Polyurethane (BD Vialon™)	Yes
	Lubricants	Silicone	Silicone	Yes
	Wedge	Stainless Steel	Stainless Steel	Yes
<b>Materials</b>	<b>Wings (Wing Inserter)</b>	PVC with <b>DOA (non-DEHP)</b> plasticizer	PVC with DEHP plasticizer	Yes; The modified plasticizer meets the existing performance acceptance criteria including force to Detach Extension Tube from Winged Inserter and Luer Adapter. BD assessed the physical properties and determined modified plasticizer resulted in the same hardness, elongation, and modulus. BD determined there is no change to performance or safety to impact the fit, form or function of the device. Biocompatibility end points were evaluated with no unacceptable risks. This change does not change the intended use or raise new or different questions of safety or effectiveness.

Attribute	Component	SUBJECT BD Saf-T-Intima™ Subcutaneous Catheter System	PREDICATE (K013800) BD Saf-T-Intima™ Intravascular Catheter	Substantially Equivalent?
	Extension Tubing	PVC with <b>DOA (non-DEHP)</b> plasticizer	PVC with DEHP plasticizer	<p>Yes;</p> <p>The modified plasticizer meets the existing performance acceptance criteria including force to Detach Extension Tube from Winged Inserter and Luer Adapter. BD assessed the physical properties and determined modified plasticizer resulted in the same hardness, elongation, and modulus. BD determined there is no change to performance or safety to impact the fit, form or function of the device.</p> <p>Biocompatibility end points were evaluated with no unacceptable risks</p> <p>This change does not change the intended use or raise new or different questions of safety or effectiveness.</p>
	<b>Clamp</b>	ABS	ABS	Yes
	<b>Adapter Wedge</b>	Stainless Steel	Stainless Steel	Yes
	<b>Y Adapter</b>	Polypropylene	Polypropylene	Yes
	<b>Vent Plug</b>	Polypropylene & Filter	Polypropylene & Filter	Yes
	<b>PRN Adapter Stopper</b>	Polyisoprene	Polyisoprene	Yes
	<b>PRN Adapter Shrink Band</b>	PVC	PVC	Yes
	<b>PRN Adapter Luer Lock</b>	Polycarbonate	Polycarbonate	Yes
	<b>Shield</b>	Polypropylene	Polypropylene	Yes
	<b>Stylet Wire</b>	Stainless Steel	Stainless Steel	Yes
	<b>Stylet Puller</b>	Polypropylene	Polypropylene	Yes
	<b>Glue</b>	Epoxy Resin	Epoxy Resin	Yes

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**Summary of Performance Tests** The following performance tests were completed on the subject device and additional limited tests completed to support the determination of substantial equivalence to the predicate device. A risk analysis per ISO 14971 was conducted to assess the impact of the proposed modifications to the predicate device. BD has determined the technological characteristics between the subject and predicate devices were found to be substantially equivalent. The results of performance testing current and new were found to be applicable to the subject device. The performance tests listed below are to ensure that the subject device meets predetermined design requirements:

1. Compliance Testing
  - ISO 80369-7
  - ISO 10555-1 / ISO 10555-7
  - ISO 23908
  - ISO 11607
  - ISO 10993-1
  - ISO 11135-1
2. BD Internal Studies
  - Peak Insertion Force
  - Catheter Drag Force
  - Style / Needle Removal Force
  - Decouple Force (Safety Shield)
3. Usability testing per *Applying Human Factors and Usability Engineering to Medical Devices Guidance for Industry and Food and Drug Administration Staff*, issued February 2016

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.

Clinical studies are not required to demonstrate substantial equivalence to the predicate device.

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**Summary of Substantial Equivalence** Based on the intended use, technological characteristics, and results of performance testing, the subject BD Saf-T-Intima™ Subcutaneous Catheter System has been demonstrated to be substantially equivalent to the predicate device.

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