April 2, 2026

Becton Dickinson Infusion Therapy Systems Inc.
Rupali Gupta
Associate Director, Regulatory Affairs
9450 South State Street
Sandy, Utah 84070

Re: K252137
Trade/Device Name: BD Insyte™ IV Catheter
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: Class II
Product Code: FOZ
Dated: February 26, 2026
Received: March 2, 2026

Dear Rupali Gupta:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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) 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
*See PRA Statement below.*

510(k) Number *(if known)*
K252137

Device Name
BD Insyte™ IV Catheter

Indications for Use *(Describe)*
BD Insyte™ 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. 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.**

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.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"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."*

Becton Dickinson Infusion Therapy Systems Inc.
9450 South State Street
Sandy, UT 84070 USA

bd.com

# K252137 - 510(k) Summary (21 CFR §807.92)

## BD Insyte™ IV Catheter

| | | |
|---|---|---|
| **Submitter Information** | Submitter Name: | Becton Dickinson Infusion Therapy Systems Inc. |
| | Submitter Address: | 9450 South State Street<br>Sandy, Utah 84070 |
| | Contact Person: | Rupali Gupta<br>Associate Director, Regulatory Affairs |
| | Email Address: | rupali.gupta@bd.com |
| | Phone Number: | (801) 522-5000 |
| | Date of Preparation: | April 01, 2026 |
| **Subject Device** | Trade Name: | BD Insyte™ IV Catheter |
| | Common Name: | Short-Term Less than 30 Days Therapeutic, Intravascular Catheter |
| | Regulation Number: | 21 CFR §880.5200 |
| | Regulation Name: | Intravascular Catheter |
| | Regulatory Class: | II |
| | Product Code: | FOZ |
| | Classification Panel: | General Hospital |
| **Predicate Device** | Trade Name: | BD Angiocath™ and BD Insyte™ IV Catheters |
| | 510(k) Reference: | K151698 |
| | Common Name: | Short-Term Less than 30 Days Therapeutic, Intravascular Catheter |
| | Regulation Number: | 21 CFR §880.5200 |
| | Regulation Name: | Intravascular Catheter |
| | Regulatory Class: | II |
| | Product Code: | FOZ |
| | Classification Panel: | General Hospital |

Becton Dickinson Infusion Therapy Systems Inc.
9450 South State Street
Sandy, UT 84070 USA

bd.com

**Reason for Submission**

The purpose of this submission is to notify CDRH that BD is updating the 510(k) baseline for BD Insyte™ IV Catheter devices (BD Insyte™, BD Insyte-W™, BD Insyte-N™) to the current state-of-the-art, which represents modifications to Becton Dickinson's own BD Insyte™ IV Catheter (K151698) as follows:

- Creation of new performance specifications for Blood Fill Time to support blood sampling; and Frequency Response and Catheter Kink Resistance to support blood pressure monitoring, as noted in the current BD Insyte™ IV Catheter indications for use statement.

- Creation of new performance specifications for existing Instaflash claim to strengthen supporting data:

    - Force to remove needle cover
    - Time to visualize flashback in flash chamber
    - Instaflash time of product with patent needles
    - Vent Plug does not fall off

- Modifications to product labeling, including the Instructions for Use, to comply with international requirements, EU MDR requirements, regulations, standards, and FDA labeling guidelines.

- Compliance with ISO 80369-7 (in place of ISO 594-1 and ISO 594-2).

- Modification to unit package top web and bottom web material formulation, as well as secondary level packaging box formulation & thickness.

- Provide design verification evidence supporting the regrind process in injection molding of the needle cover and needle hub component.

- Additional minor changes to the BD Insyte™ IV Catheter product materials, design, performance specifications, and primary packaging that were previously implemented via letter-to-file have been consolidated in this submission. This 510(k) provides FDA with information on the currently marketed device (subject device) along with supporting testing needed to demonstrate continued substantial equivalence.

Becton Dickinson Infusion Therapy Systems Inc.
9450 South State Street
Sandy, UT 84070 USA

bd.com

| | |
|---|---|
| **Device Description** | BD Insyte™ IV Catheter is a conventional (non-safety) over-the-needle intravascular (IV) catheter. BD Insyte™ IV Catheter has a radiopaque BD Vialon™ Catheter Material. This device includes a needle and flash chamber with removable vent plug. The needle and catheter are protected by a needle cover.<br><br>BD Insyte-N™ IV Catheter has BD Instaflash™ Needle Technology, allowing for immediate visualization of blood along the catheter. The flash chamber on all devices provides confirmation that the catheter has entered the vessel.<br><br>BD Insyte™ IV Catheter is available without wings. BD Insyte-W™ IV Catheter is only available with wings. BD Insyte-N™ 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).<br><br>BD Insyte™ IV Catheter 22-18 GA (0.9-1.3 mm) 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))** | BD Insyte™ 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. 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 BD Insyte™ IV Catheter device is substantially equivalent to the predicate device. The subject BD Insyte™ IV Catheter (Insyte™, Insyte-W™, and Insyte-N™) achieves its intended use based on the same technology and principles of operation as the predicate device.<br><br>Comparisons of the subject and predicate devices technological characteristics are provided in Tables 1-1, 1-2, and 1-3 below. |

Becton Dickinson Infusion Therapy Systems Inc.
9450 South State Street
Sandy, UT 84070 USA

bd.com

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

| Attribute | SUBJECT<br>Insyte™ IV Catheters | PREDICATE<br>(K151698)<br>Insyte™ IV Catheters | Substantial Equivalent? |
|---|---|---|---|
| **Classification** | 21 CFR 880.5200<br>Class II<br>FOZ - Intravascular Catheter | 21 CFR 880.5200<br>Class II<br>FOZ - Intravascular Catheter | Yes<br>Same as predicate |
| **Indications for Use** | BD Insyte™ 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). | An intravascular catheter is a device 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<br>The indications for use statements have been revised to include word clarification, information on patient population as well as power injection to align with current requirements. These revisions serve to clarify current product use in clinical practice and align with the indications for use of other BD PIVC devices (e.g., BD Nexiva Diffusics (K250682), BD Insyte Autoguard Shielded IV Catheter, BD Insyte Autoguard BC Shielded IV Catheter and BD Insyte Autoguard BC Pro Shielded IV Catheter (K251654).<br>These updates do not change the intended use of the product or introduce new features or functionality; there are no new questions of safety or effectiveness. |
| **Intended Use** | Intravascular access | Intravascular access | Yes<br>Same as predicate |
| **Fundamental Scientific Technology** | Peripheral intravascular catheter | Peripheral intravascular catheter | Yes<br>Same as predicate |
| **Catheter Dimensions** | Catheter Diameter and lengths<br>14G x 1.75 IN (3.1mm)<br>16G x 1.16 IN (1.7mm)<br>16G x 1.77 IN (1.7mm)<br>18G x 1.16 IN (1.3mm)<br>18G x 1.88 IN (1.3mm) | Catheter Diameter and lengths<br>14G x 1.75 IN (3.1mm)<br>16G x 1.16 IN (1.7mm)<br>16G x 1.77 IN (1.7mm)<br>18G x 1.16 IN (1.3mm)<br>18G x 1.88 IN (1.3mm) | Yes<br>Same as predicate |

Becton Dickinson Infusion Therapy Systems Inc.
9450 South State Street
Sandy, UT 84070 USA

bd.com

| Attribute | SUBJECT<br>Insyte™ IV Catheters | PREDICATE<br>(K151698)<br>Insyte™ IV Catheters | Substantial Equivalent? |
|---|---|---|---|
| | 20G x 1.00 IN (1.1 mm)<br>20G x 1.16 IN (1.1 mm)<br>20G x 1.88 IN (1.1 mm)<br>22G x 1.00 IN (0.9 mm)<br>24G x 0.56 IN (0.7 mm)<br>24G x 0.75 IN (0.7 mm) | 20G x 1.00 IN (1.1 mm)<br>20G x 1.16 IN (1.1 mm)<br>20G x 1.88 IN (1.1 mm)<br>22G x 1.00 IN (0.9 mm)<br>24G x 0.56 IN (0.7 mm)<br>24G x 0.75 IN (0.7 mm) | |
| **Product Configurations** | Winged<br>Non-Winged | Winged<br>Non-Winged | Yes<br>Same as predicate |
| **Sterilization Modality** | Ethylene oxide (EO) | Ethylene oxide (EO) | Yes<br>Same as predicate |
| **Sterilization Sites** | BD Curitiba<br>BD Tuas or BD Sterile Services | BD Curitiba<br>BD Tuas or BD Sterile Services | Yes<br>Same as predicate |
| **Minimum SAL (Sterility)** | $1 \times 10^{-6}$ | $1 \times 10^{-6}$ | Yes<br>Same as predicate |
| **Shelf Life** | 5 years | 5 years | Yes<br>Same as predicate |
| **Energy Source** | User operated | User operated | Yes<br>Same as predicate |
| **Disposable or Reusable** | Disposable | Disposable | Yes<br>Same as predicate |
| **Use Environment** | • Professional Healthcare Facility<br>• Magnetic Resonance (MR) Environment<br>• Transport (Ambulatory) Environment | • Professional Healthcare Facility<br>• Magnetic Resonance (MR) Environment<br>• Transport (Ambulatory) Environment | Yes<br>Same as predicate |
| **Performance Testing** | **Performance**<br>ISO 80369-7<br>ISO 10555-1/ISO 10555-5<br>ISO 11607<br>ISO 10993-1<br>ISO 11135-1<br>**Shipping**<br>ASTM D4169<br>**Aging**<br>ASTM F1980<br>BD Internal Requirement(s) | **Performance**<br>ISO 80369-7<br>ISO 10555-1/ISO 10555-5<br>ISO 11607<br>ISO 10993-1<br>ISO 11135-1<br>**Shipping**<br>ASTM D4169<br>**Aging**<br>ASTM F1980<br>BD Internal Requirement(s) | Dimension and performance testing per ISO 80369-7:2021.<br><br>ISO 594-1 and ISO 594-2 have been withdrawn and replaced by ISO 80369-7 which is now recognized by the FDA. |

Becton Dickinson Infusion Therapy Systems Inc.
9450 South State Street
Sandy, UT 84070 USA

bd.com

**Table 1-2 Comparison of Subject / Predicate Device & Packaging Materials**

| Attribute | SUBJECT<br>Insyte™ IV Catheters | PREDICATE<br>(K151698)<br>Insyte™ IV Catheters | Substantial Equivalence? |
|---|---|---|---|
| **Needle (Cannula)** | 304 Stainless Steel | Stainless Steel | Yes<br>Same as predicate |
| **Needle Lubricant** | Polydimethylsiloxane | Polydimethylsiloxane | Yes<br>Same as predicate |
| **Catheter (Catheter Tubing)** | BD Vialon ™ Polyurethane | BD Vialon ™ Polyurethane | Yes<br>Same as predicate |
| **Catheter Lubricant** | Polydimethylsiloxane | Polydimethylsiloxane | Yes<br>Same as predicate |
| **Catheter Tipping Lubricant** | Polydimethylsiloxane | Polydimethylsiloxane | Yes<br>Same as predicate |
| **Needle Hub** | Propionate | Propionate | Yes<br>Same as predicate |
| **Needle Cover** | Polypropylene | Polypropylene | Yes<br>Same as predicate |
| **Metal Wedge** | Stainless Steel | Stainless Steel | Yes<br>Same as predicate |
| **Wedge Lubricant** | Polydimethylsiloxane | Polydimethylsiloxane | Yes<br>Same as predicate |
| **Vent Plug** | Polypropylene (plug)<br>Acrylic copolymer (filter) | Polypropylene (plug)<br>Acrylic copolymer (filter) | Yes<br>Same as predicate |
| **Catheter Adapter**<br>**(with and without wings)** | Polypropylene | Polypropylene | Yes<br>Same as predicate |
| **Catheter Adapter Colorants** | Polypropylene + Colorant<br>24 GA (Yellow)<br>22 GA (Blue)<br>20 GA (Pink)<br>18 GA (Green)<br>16 GA (Gray)<br>14 GA (Orange) | Polypropylene + Colorant<br>24 GA (Yellow)<br>22 GA (Blue)<br>20 GA (Pink)<br>18 GA (Green)<br>16 GA (Gray)<br>14 GA (Orange) | Biocompatibility Testing per ISO 10993-1:2018, 10993-3, 10993-11, 10993-12, 10993-18 |
| **Adhesive (Glue)** | Epoxy Resin + Polyamide curing agent | Epoxy Resin + Polyamide curing agent | Yes<br>Same as predicate |

Becton Dickinson Infusion Therapy Systems Inc.
9450 South State Street
Sandy, UT 84070 USA

bd.com

| Attribute | SUBJECT<br>Insyte™ IV Catheters | PREDICATE<br>(K151698)<br>Insyte™ IV Catheters | Substantial Equivalence? |
|---|---|---|---|
| **Top Web** | Medical Grade Paper | Medical Grade Paper | Unit Packaging Testing per ISO 11607-1:2019<br>Biocompatibility Testing per ISO 10993-1:2018 |
| **Bottom Web** | Nylon Thermoforming Film | Copolymer Resin | Unit Packaging Testing per ISO 11607-1<br>Biocompatibility Testing per ISO 10993-1:2018 |

**Summary of Performance Tests**

The following performance tests were completed on the subject device to support the determination of substantial equivalence to the predicate device.

A risk analysis was conducted in accordance with *ISO 14971:2019 Medical Devices – Application of Risk Management to Medical Devices* 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 following guidance documents and standards in conjunction with in-house protocols were used to determine appropriate methods for evaluating the performance of the device:

1. Compliance Testing
    - Testing per ISO 10555-1:2013 + Amd 1:2017, ISO 10555-5:2013, ISO 80369-7:2021
    - Packaging validation per ISO 11607-1:2019
    - Biological evaluation per ISO 10993-1:2018
    - EO residuals per ISO 10993-7:2008
    - Sterilization validation per ISO 11135-1:2014
2. BD Internal Requirements
    - Package Peal Force
    - Package Integrity Test
    - Catheter to Adapter Separation Force
    - Needle-to-Hub Pull Force

- Needle Cover remains in place
- Vent Plug does not fall off
- Frequency Response
- Catheter tubing shall not kink or create a crease in the tubing wall
- Blood Fill Time shall be measured
- Force to Remove Needle Cover
- Chamber Flashback Visible at Needle Hub
- Instaflash Time
- Power Injection

A biocompatibility evaluation, in accordance with *ISO 10993-1:2018, Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process* and *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 September 2023)*, was conducted. The following testing was undertaken to support the biocompatibility of the subject devices:

- Cytotoxicity per ISO 10993-5:2009
- Sensitization per ISO 10993-10:2021
- Intracutaneous Reactivity per ISO 10993-23:2021
- Acute Systemic Toxicity per ISO 10993-11:2017
- Material-mediated Pyrogenicity per ISO 10993-11:2017 & USP <151>
- Subacute/Subchronic Toxicity per ISO 10993-11:2017
- Genotoxicity per ISO 10993-3:2014
- Implantation per ISO 10993-6:2016
- Hemocompatibility per ISO 10993-4:2017 & ASTM F756-17
- Particulate Matter per USP <788> & per acceptance criteria in ISO 8536-4:2019

Per design control requirements specified in 21 CFR §820.30, the subject device met all predetermined acceptance criteria for the above-listed performance tests, demonstrating substantial equivalence to the predicate device.

| | |
|---|---|
| **Summary of Substantial Equivalence** | Based on the risk management activities, identical intended use, technological characteristics, and results of performance testing, the subject BD Insyte™ IV Catheter is considered substantially equivalent to the predicate device. |