



March 6, 2024

CareFusion
Stefanee Smith
Senior Regulatory Affairs Specialist
10020 Pacific Mesa Blvd.
San Diego, California 92121

Re: K233021

Trade/Device Name: BD SmartSite™ 13mm Vial Access Device; BD SmartSite™ 20mm Vial Access Device
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: LHI
Dated: February 5, 2024
Received: February 5, 2024

Dear Stefanee Smith:

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.

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,



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)

K233021

Device Name

BD SmartSite™ 13mm Vial Access Device;

BD SmartSite™ 20mm Vial Access Device

Indications for Use (Describe)

Vial access devices with SmartSite™ are standalone, single-vial use, disposable devices which provide access to a medication vial without the use of a needle during medication preparation. BD standalone vial access devices are not intended to be used on a patient.

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
PRASStaff@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."

K233021-510(k) Summary

Submitter Information

Submitter: CareFusion
10020 Pacific Mesa Blvd.
San Diego, CA 92121, USA

Contact Person: Stefanee Smith
Phone: 717-330-6037
Email: stefanee_smith@bd.com
Date Prepared: March 6, 2024

Subject Device Identification

Trade Name: BD SmartSite™ 13mm Vial Access Device;
BD SmartSite™ 20mm Vial Access Device

Common Name: IV Fluid Transfer Set

Regulation Name: Intravascular Administration Set

Review Panel: General Hospital

Regulation Number: 21 CFR 880.5440

Regulatory Class: Class II

Product Code: LHI

Predicate Device Identification

Trade Name: SmartSite Access Pin

Common Name: IV Fluid Transfer Set

Regulation Name: Intravascular Administration Set

Review Panel: General Hospital

Regulation Number: 21 CFR 880.5440

Regulatory Class: Class II

Product Code: LHI and FPA

Manufacturer: IVAC Holdings, Incorporated (Now BD)

510k Number: K970485

Device Description

Vial access devices with SmartSite™ are standalone, single-vial use, disposable devices which permit access to a medication vial without the use of a needle during medication preparation. Vial access devices with needle-free connectors are available in two configurations: 13 mm or 20 mm.

Intended Use

The BD SmartSite™ Vial Access Device is for use with medication vials and mating luer access devices for withdrawal and/or injection of fluid.

Indications for Use

Vial access devices with SmartSite™ are standalone, single-vial use, disposable devices which provide access to a medication vial without the use of a needle during medication preparation. BD standalone vial access devices are not intended to be used on a patient.

Technological Characteristics

The BD SmartSite™ Vial Access Device was shown to be substantially equivalent to the predicate device cleared under K970485. Differences in technological characteristics such as the material were addressed through biocompatibility and performance testing. The following table presents an overview of comparisons between the subject and predicate device.

Technological Characteristics and Substantial Equivalence

The following table provides an overview of comparisons between the subject and the predicate device.

Attributes	Subject Device: BD SmartSite™ 13mm Vial Access Device; BD SmartSite™ 20mm Vial Access Device	Predicate Device: SmartSite Access Pin	Equivalence Discussion
510(k) Status	K233021	K970485 Clearance date April 21, 1997	N/A
Applicant	CareFusion (Now BD)	IVAC Holdings, Incorporated (Now BD)	N/A
Model Number(s)	2203E and 2205E	2202E	N/A
Indications for use	Vial Access devices with SmartSite™ are standalone, single-vial use, disposable devices which provide access to a medication vial without the use of a needle during medication preparation. BD standalone vial access devices are not intended to be used on a patient.	The SmartSite Access Pin is intended to be used for intravenous administration of drugs and fluids (e.g., blood, lipids, saline, and dextrose).	Similar – The exception being the subject device is only used for medication preparation and not intended to be used on a patient. The difference does not raise different questions of safety and effectiveness.

Attributes	Subject Device: BD SmartSite™ 13mm Vial Access Device; BD SmartSite™ 20mm Vial Access Device	Predicate Device: SmartSite Access Pin	Equivalence Discussion
Device Components / Materials	<p><u>Vial Adaptor Body & Spike:</u> Makrolon (Polycarbonate RX2530- 451118)</p> <p><u>SmartSite Female Luer:</u> Isoplast (2530 Polyurethane)</p> <p><u>Piston:</u> Silicone (Elastosil LR3003/80) with 3% DOW Corning 550 Fluid</p> <p><u>Lubricant (piston opening):</u> Silicone fluid (FS-1265 Fluorosilicone Fluid)</p>	<p><u>Access Pin Body:</u> Makrolon (Polycarbonate RX2530- 451118)</p> <p><u>SmartSite Female Luer:</u> Isoplast (2530 Polyurethane)</p> <p><u>Piston:</u> Silicone (Elastosil LR3003/80)</p> <p><u>Spike Plastic:</u> Valox (Polybutylene Terephthalate HX420HP-1H1001)</p> <p><u>Lubricant (piston opening):</u> Silicone fluid (FS-1265 Fluorosilicone Fluid)</p> <p><u>Lubricant:</u> Silicone fluid (550 Silicone Fluid)</p>	Biocompatibility results on the subject devices show that the materials are safe per the intended use.
Piercing Spike	<u>Single Lumen</u>	<u>Single Lumen</u>	Same
Vial Adapter Fit	<u>Snap Fit to Vial</u>	<u>Spring Clip</u>	Different-There is a difference in vial adapter fit for the two devices. The subject device has 4 tabs on the vial adapter body and the predicate device has 2 tabs on the access pin body to secure the device to the vial. The 4 tabs

Attributes	Subject Device: BD SmartSite™ 13mm Vial Access Device; BD SmartSite™ 20mm Vial Access Device	Predicate Device: SmartSite Access Pin	Equivalence Discussion
			facilitate a more secure connection with the vial due to the higher surface area of Performance bench testing demonstrates the difference does not raise different questions of safety and effectiveness.
Compatible vial size	<u>13mm and 20mm</u>	<u>Variable</u>	Different - The predicate device is a universal adapter designed to fit different vial sizes. The subject device is designed to fit a 13mm or 20mm vial size. Performance bench testing demonstrates the difference does not raise different questions of safety and effectiveness.
Prescription Use	<u>Yes</u>	<u>Yes</u>	Same
Packaging Configuration	Each device is individually packaged in pouches. Fifty (50) pouches and one (1) Directions for Use per dispenser box. Two (2) dispenser boxes per shipper box.	Each device is individually packaged in pouches. Fifty (50) pouches and one (1) Directions for Use per dispenser box. Two (2) dispenser boxes per shipper box.	Same
Packaging Type	Peelable Tyvek/Film Pouch	Peelable Tyvek/Film Pouch	Same
Sterilization Method	Radiation (SAL 10 ⁻⁶)	Radiation (SAL 10 ⁻⁶)	Same
Non-Pyrogenic	Yes	Yes	Same

Attributes	Subject Device: BD SmartSite™ 13mm Vial Access Device; BD SmartSite™ 20mm Vial Access Device	Predicate Device: SmartSite Access Pin	Equivalence Discussion
Residual Volume	0.07 mL	Unknown	Residual volume has no impact on the safety and effectiveness of the device. It is provided as an additional input for the end user to inform the amount of drug volume that could be potentially left in the subject device.
Method of Disinfection	Prior to every access, swab top of NFC access surface for 2 – 5 seconds with 70% isopropyl alcohol and allow to dry	Prior to every access, swab top of Needle-Free Valve port with 70% isopropyl alcohol (1 – 2 seconds) and allow to dry (approximately 30 seconds)	Different - the longer swab time does not raise new or different questions of safety and effectiveness.
Use	Single Vial Use	Single Vial Use	Same
Shelf Life	3 years	3 years	Same

Substantial Equivalence Discussion:

Design verification testing was performed to demonstrate that the subject device is substantially equivalent to the predicate device. All test results met their acceptance criteria and support that the BD SmartSite™ Vial Access Device is substantially equivalent to the predicate SmartSite Access Pin. The subject device and the predicate have equivalent indications for use and intended use. Both devices are sterilized via irradiation and are single vial use devices.

Both the subject and predicate devices have the same principle of operation. The BD SmartSite™ Vial Access Device contains minor differences in technological characteristics when compared to the predicate device, these differences do not change the intended use and do not raise new questions of safety and effectiveness as supported by verification testing.

Safety and Performance Testing

Nonclinical Testing:

The BD SmartSite™ Vial Access Device was evaluated via non-clinical safety and performance testing to demonstrate that the subject device is substantially equivalent to the predicate device.

The bench and nonclinical testing on the BD SmartSite™ Vial Access Device were conducted according to the following FDA recognized consensus standards listed below. The subject device met the applicable test specifications and acceptance criteria as described in the submission.

- ISO 594-1:1986, Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirements (FDA Recognition Number 6-11)
- ISO 594-2:1998, Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 2: Lock fittings (FDA Recognition Number 6-129)
- ISO 80369-7:2021, Small-bore connectors for liquids and gases in healthcare

applications – Part 7: Connectors for intravascular or hypodermic applications (FDA Recognition Number 5-133)

- ISO 22413:2021, Transfer sets for pharmaceutical preparations – Requirements and test methods
- ISO 11137-1:2006, Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices [Including: Amendment 1 (2013) and Amendment 2 (2018)] (FDA Recognition Number 14-528)
- ISO 11137-2:2013, Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose (FDA Recognition Number 14-409)
- ISO 11137-3:2017, Sterilization of health care products – Radiation – Part 3: Guidance on dosimetric aspects (FDA Recognition Number 14-510)
- ISO 11737-1:2018, Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on product [Including: Amendment 1 (2021)] (FDA Recognition Number 14-577)
- ISO 11737-2:2019 Sterilization of health care products – Part 2: Microbiological methods – Tests of sterility performed in the definition, validation and maintenance of a sterilization process (FDA Recognition Number 14-540)
- ISO 11607-1:2019, Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (FDA Recognition Number 14-530)
- ISO 11607-2:2019, Packaging for Terminally Sterilized Medical Devices – Part 2: Validation Requirements for Forming, Sealing and Assembly Processes (FDA Recognition Number 14-531)
- ASTM F2096 and ASTM F2096-11, Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test) (FDA Recognition Number 14-359)

Biocompatibility:

Biocompatibility tests for the subject device were performed in accordance with ISO 10993-1, Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process as recognized by the FDA. The BD SmartSite™ Vial Access Device is categorized as an externally communicating tissue contacting (indirect) prolonged (> 24 hours to 30 days) device in accordance with ISO 10993-1 and FDA Guidance, Use of

International Standard 10993-1, "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process." The battery of tests included the following:

- Cytotoxicity (ISO 10993-5:2009, FDA Recognition Number 2-245)
- Genotoxicity (ISO 10993-3:2014, FDA Recognition Number 2-228)
- Sensitization (ISO 10993-10:2021, FDA Recognition Number 2-296)
- Irritation / Intracutaneous Reactivity (ISO 10993-23:2021, FDA Recognition Number 2-291)
- Acute Systemic Toxicity (ISO 10993-11:2017, FDA Recognition Number 2-255)
- Sub-acute/ Sub-chronic Toxicity (ISO 10993-11:2017, FDA Recognition Number 2-255)
- Material Mediated Pyrogenicity (ISO 10993-11:2017, FDA Recognition Number 2-255)
- Hemolysis Indirect (ISO 10993-4:2017, FDA Recognition Number 2-248)
- Chemical Requirements; Section 8 (ISO 8536-4:2019, FDA Recognition Number 6-447)

Particulate Testing:

The BD SmartSite™ Vial Access Device was tested to demonstrate the product meets particulate requirements of United States Pharmacopeia, National Formulary (USP), General Chapter <788>, Particulate Matter in Injections (Current Standard).

Microbial Ingress Testing:

Microbial ingress was performed based on the following FDA guidance document:

- Guidance for Industry and FDA staff; Intravascular Administration Sets Premarket Notification Submissions [510(k)], July 11, 2008

Additional evaluation was conducted to simulate use with fluids:

- Harsh Infusates testing

Clinical Data:

Not Applicable. Clinical data was not considered necessary to demonstrate substantial equivalence to the predicate device.

Conclusion:

The information provided in this submission, including the non-clinical safety and performance testing, adequately demonstrates substantial equivalence of the BD SmartSite™ 13mm Vial Access Device; BD SmartSite™ 20mm Vial Access Device to the predicate device, cleared under K970485. The BD SmartSite™ 13mm Vial Access Device;

BD SmartSite™ 20mm Vial Access Device and the predicate device have similar indications for use, the same intended use, and similar technological characteristics. Any differences between the subject and predicate device do not raise new questions of safety and effectiveness.