April 7, 2023

CareFusion
Jacob Lee
Sr. Manager Regulatory Affairs
10020 Pacific Mesa Blvd
San Diego, California 92121

Re: K223088
Trade/Device Name: BD SmartSite™ Needle-Free Connector
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: FPA
Dated: March 8, 2023
Received: March 8, 2023

Dear Jacob Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

David Wolloscheck, Ph.D.
Acting 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223088

Device Name
BD SmartSite™ Needle-Free Connector

Indications for Use *(Describe)*
The BD SmartSite™ Needle-Free Connector (NFC) is a sterile, single patient use connector for needle free access to the IV line and/or IV catheter during IV therapy. The BD SmartSite™ NFC can be used for direct injection, intermittent infusion and/or the continuous infusion of fluids, drugs, IV nutrition, lipids, and/or blood/blood products or the aspiration of blood. The BD SmartSite™ NFC may be used with power injector procedures to a maximum pressure of 325 psi up to a flow rate of 10 mL per second.

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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K223088 -
510(k) Summary

Submitter Information

Submitter:	CareFusion 10020 Pacific Mesa Blvd. San Diego, CA 92121, USA
Contact Person:	Jacob Lee
Phone:	385-255-0184
Email:	jacob.lee@bd.com
Date Prepared:	April 7, 2023

Subject Device Identification

Trade Name:	BD SmartSite™ Needle-Free Connector
Common Name:	Intravascular Administration Set
Classification Name:	Intravascular Administration Set
Classification Panel:	General Hospital
Regulation Number:	21 CFR 880.5440
Regulatory Class:	Class II
Product Code:	FPA

Predicate Device Identification

Trade Name:	SmartSite™ Needle-Free Valve
Common Name:	Intravascular Administration Set
Classification Name:	Intravascular Administration Set
Classification Panel:	General Hospital
Regulation Number:	21 CFR 880.5440
Regulatory Class:	Class II
Product Code:	FPA
Manufacturer:	CareFusion, Inc.
510k Number:	K061285
510K Clearance Date:	July 26, 2006

Reason for Submission

The objective of this submission is to introduce new labeling claims. Specifically, the following claims are proposed to be added to the labeling:

- Duration of use to 7 days (168 hours) or 200 activations, whichever occurs first
- Sterility claim from fluid path sterile to content sterile
- Update disinfection swab time

Device Description

The BD SmartSite™ NFC allows the user to add medication into the primary line without the use of a needle. It consists of a female luer on one side and a male luer connection on the other side. Both connections have locking threads. The connector has a silicone valve inside which is in an expanded position in the free state. When the male luer end of a compatible vascular access device is attached securely to the female luer of the SmartSite connector, the valve/piston is compressed which opens the fluid pathway. This open pathway allows administration of fluids as well as aspiration through the connector without the use of a needle.

Indication for Use

The BD SmartSite™ Needle-Free Connector (NFC) is a sterile, single patient use connector for needle free access to the IV line and/or IV catheter during IV therapy. The BD SmartSite™ NFC can be used for direct injection, intermittent infusion and/or the continuous infusion of fluids, drugs, IV nutrition, lipids, and/or blood/blood products or the aspiration of blood. The BD SmartSite™ NFC may be used with power injector procedures to a maximum pressure of 325 psi up to a flow rate of 10 mL per second.

Technological Characteristics

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

Attributes	Subject: BD SmartSite™ Needle-Free Connector	SmartSite Needle Free Valve (K061285)	Equivalence Discussion
FDA Reg. Number	21 CFR 880.5440	21 CFR 880.5440	Same
FDA Regulation Name	Intravascular Administration Set	Intravascular Administration Set	Same
FDA Class	Class II	Class II	Same
FDA Product Code	FPA	FPA	Same
Indication for use	The BD SmartSite™ Needle-Free Connector (NFC) is a sterile, single patient use connector for needle free access to the IV line and/or IV catheter during IV therapy. The BD SmartSite™ NFC can be used for direct injection, intermittent infusion and/or the continuous infusion of fluids, drugs, IV nutrition, lipids, and/or blood/blood products or the aspiration of blood. The BD SmartSite™ NFC may be used with power injector procedures to a maximum pressure of 325 psi up to a flow rate of 10 mL per second.	The SmartSite Needle Free Valve Administration Sets are intended for use in today's growing professional healthcare environment including healthcare facilities, home care, and medical transport that utilize infusion systems for the delivery of fluids, medication, blood and blood products. The SmartSite valve allows the user to add medication into the primary line without the use of a needle. The SmartSite valve also be used with low pressure power injectors rated for a maximum setting of 325 psi.	Different – mechanical hemolysis and blood compatibility was conducted to verify blood aspiration claim

Attributes	Subject: BD SmartSite™ Needle-Free Connector	SmartSite Needle Free Valve (K061285)	Equivalence Discussion
Device Components / Materials	SmartSite Body and Male Luer: Acrylic Multi-polymer (GS90) SmartSite Female Luer: Isoplast (2530 Polyeurethane) Piston: Silicone (Elastosil LR3003/80) Lubricant (piston opening): Silicone fluid (FS-1265 Fluorosilicone Fluid) Lubricant: Silicone fluid (550 Silicone Fluid)	SmartSite Body and Male Luer: Acrylic Multi-polymer (GS90) SmartSite Female Luer: Isoplast (2530 Polyeurethane) Piston: Silicone (Elastosil LR3003/80) Lubricant (piston opening): Silicone fluid (FS-1265 Fluorosilicone Fluid) Lubricant: Silicone fluid (550 Silicone Fluid)	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
Sterilization Method	Radiation (SAL 10^{-6})	Radiation (SAL 10^{-6})	Same
Sterilization Claim	Content Sterile	Fluid Path Sterile	Different – Package integrity testing was conducted to verify sterile barrier claim.
Biocompatibility	Biocompatible for the intended use per ISO 10993-1	Biocompatible for the intended use per ISO 10993-1	Same
Non-Pyrogenic	Yes	Yes	Same
Non-DEHP	Yes	Yes	Same
No Natural Rubber Latex	Yes	Yes	Same

Attributes	Subject: BD SmartSite™ Needle-Free Connector	SmartSite Needle Free Valve (K061285)	Equivalence Discussion
Duration of Use	7 days (168 hours)	72 hours; 24 hours for infusions of blood, blood products or lipids emulsions	Different – All intended fluids per indications extended to 7 day duration. verification testing was conducted to extend the device duration. See Section 18 for Harsh Infusate testing.
Priming Volume	0.1 mL	0.11 mL	Equivalent - the priming volume is within the specification of the predicate and has no impact on functional or performance characteristics.
Residual Volume	0 mL	0 mL	Same
Number of Valve Activations	200	100	Different – verification conducted to extend number of valve activations.
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 or effectiveness.
Power Infusion Flow Rate	≤ 325 psi; 10 mL/s	Maximum 325 psi	Equivalent
Use	Single Patient Use	Single Patient Use	Same
Shelf Life	3 years	3 years	Same

Substantial Equivalence Discussion:

Design verification testing was performed to demonstrate that the subject device is equivalent to the predicate device. All test results met their acceptance criteria and support that the BD SmartSite™ NFC is safe and effective and is substantially equivalent to the predicate SmartSite Needle Free Valve. The subject device and the predicate have the equivalent indications for use and intended use. Both devices are sterilized via irradiation and are single patient use devices.

Both the subject and predicate devices have the same principle of operation. The primary technological differences between the subject device and the predicate are similar. The BD SmartSite™ NFC has a longer duration of use (up to 7 days or 200 activations, whichever comes sooner). The BD SmartSite™ NFC is also claiming content sterile and the predicate claims fluid path sterile.

The BD SmartSite™ NFC 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.

Discussion of Non-Clinical Tests:

The BD SmartSite™ NFC, like the predicate device, was evaluated for biocompatibility appropriate to the contact characterization (externally communicating, blood path (indirect) for prolonged duration (> 24 hours to 30 days)). Testing is performed in accordance with the requirements of ISO 10993-1 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process, and the FDA Guidance for Industry - Use of International Standard ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.
Specific testing included:

- ISO 10993-4:2017 Biological evaluation of medical device – Part 4: Selection of tests for interactions with blood
- ISO 10993-5:2009 Biological evaluation of medical device – Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2021 Biological evaluation of medical device – Part 10: Tests for skin sensitization
- ISO 10993-11:2017 Biological evaluation of medical device – Part 11: Tests for systemic toxicity
- ISO 10993-23:2021 Biological evaluation of medical device – Part 23: Test for irritation

Other standards followed included:

- ISO 8536-4:2019 Infusion equipment for medical use – Part 4: Infusion Sets for Single Use Gravity Feed, Section 8 Chemical and Biological Requirements

- USP <788>:2021 Particulate Matters in Injection

Particulate Testing:

The BD SmartSite™ NFC 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).

Sterilization and Shelf Life:

The subject device is radiation sterilized and data supports a shelf-life claim of 3 years. Sterilization and shelf-life testing were completed in accordance with the following FDA recognized guidelines:

Sterilization:

- 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)]
- ISO 11137-2:2013 Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose
- United States Pharmacopeia, National Formulary (USP), General Chapter <85>, Bacterial Endotoxins Test
- United States Pharmacopeia, National Formulary (USP), General Chapter <161>, Medical Devices – Bacterial Endotoxin and Pyrogen Tests
- ANSI/AAMI ST72:2019 – Bacterial endotoxins – Test methods, routine monitoring and alternatives to batch testing

Shelf-Life:

- ISO 11607-1:2019 Packaging for Terminally Sterilized Medical Devices – Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging Systems
- ISO 11607-2:2019 Packaging for Terminally Sterilized Medical Devices – Part 2: Validation Requirements for Forming, Sealing and Assembly Processes
- Package testing included:
    - Standard Test Method for Determining Integrity of seals for Flexible Packaging by Visual Inspection: ASTM F1886
    - Standard Test Method for Seal Strength of Flexible Barrier Materials: ASTM F88/F88M-21
    - Seal Transfer Width: Internal testing
    - Bubble Leak Detection Test: ASTM F2096 and ASTM F2096-11
    - Ink Legibility: Internal testing
    - Standard Test Method for Thickness Measurement of Flexible Packaging Material: ASTM F2251-13

- Label Adhesion: Internal Testing
- Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration: ASTM F1929

Performance Testing:

The BD SmartSite™ NFC was tested to verify compliance with the relevant sections of the following standards:

- ISO 8536-4:2019 Infusion equipment for medical use – Part 4: Infusion sets for single use, gravity feed
- ISO 594-1: 1986 Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirements
- ISO 594-2: 1998 Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings

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 performance testing was conducted to simulate use with fluids:

- Harsh Infusates testing: Device tests for multiple days with worst case infusates

Clinical Data:

There are no clinical data included in this submission.

Conclusion:

The information in this submission supports the safety and efficacy of the subject device for its intended use and demonstrates substantial equivalence with the predicate device. The BD SmartSite™ NFC differences in geometry, materials and sterilization claim do not raise new questions of safety and effectiveness.