May 12, 2023

CareFusion
Paulina Davis
Staff Regulatory Affairs Specialist
10020 Pacific Mesa Blvd
San Diego, California 92121

Re: K223101
Trade/Device Name: BD Secondary Infusion Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: FPA
Dated: April 12, 2023
Received: April 13, 2023

Dear Paulina Davis:

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)*
K223101

Device Name
BD Secondary Infusion Set

Indications for Use *(Describe)*
The BD Secondary Set is indicated for continuous or intermittent delivery of IV fluids, medications, including lipids, through intravascular routes of administration. The BD Secondary Set may be used with any patient population with consideration given to the procedure being performed and fluids being infused.

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.

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510(k) SUMMARY
K223101

Submitter Information	Submitter Name: Submitter Address: Contact Person: Date of Preparation:	CareFusion 10020 Pacific Mesa Blvd San Diego, CA 92121, USA Paulina Davis Staff Regulatory Affairs Specialist Phone: 714-330-6037 Email Address: Paulina.Davis@BD.com May 8, 2023
Subject Device	Trade Name: Common Name: Regulation Name: Classification Panel: Regulation Number: Regulatory Class: Product Code:	BD Secondary Infusion Set Intravascular Administration Set and Extension Set Intravascular Administration Set General Hospital 21 CFR 880.5440 Class II FPA
Predicate Device	Trade Name: Premarket Notification #: Regulation Name: Classification Panel: Regulation Number: Regulatory Class: Product Code: Manufacturer:	Intravascular Administration Set and Extension Set K051499 Intravascular Administration Set General Hospital 21 CFR 880.5440 Class II FPA Medegen Medical Manufacturing Services (Now owned by Becton, Dickinson and Company)

Reason for Submission	CareFusion is submitting this traditional premarket notification for the BD Secondary Infusion Set in support of a new 510(k) baseline for the Secondary Infusion Set.
Device Description	The BD Secondary Infusion Set is an administration set consisting primarily of a bag spike, drip chamber, tubing, roller clamp, micro luer lock connector, and a hanger. The drip chamber cap is located at the proximal end of the administration set, and the micro luer lock cap is located at the distal end of the administration set. The bag spike, located on the proximal end of the drip chamber is inserted into a prepared fluid container. The BD Secondary Infusion Set is supplied as fluid-path sterile using gamma irradiation in a perforated pouch, is non-pyrogenic, and is for

	single-use only. The BD Secondary Infusion Set is for gravity administration. The device is intended for prescription use (RX) only. DEHP or natural rubber latex are not part of the material formulation. The set can be used for up to 7 days (168 hours) provided the set is continuously attached to the primary administration set.
Intended Use	The BD Secondary Infusion Set is intended for the intravascular administration of fluids from a container to a patient's vascular system.
Indications for Use	The BD Secondary Set is indicated for continuous or intermittent delivery of IV fluids, medications, including lipids, through intravascular routes of administration. The BD Secondary Set may be used with any patient population with consideration given to the procedure being performed and fluids being infused.
Technological Characteristics	The BD Secondary Infusion Set was shown to be substantially equivalent to the predicate device cleared per K051499. Any differences in technological characteristics such as the material were addressed through biocompatibility and performance testing. The biocompatibility and performance data demonstrated substantial equivalence. There were no new questions of safety or effectiveness.

The following table provides a comparison between the subject and the predicate device.

Characteristic	Subject Device: BD Secondary Infusion Sets	Predicate Device: Intravascular Administration and Extension Sets	Equivalence Discussion
510(k) Status	Subject of 510(k)	K051499 Clearance date June 22, 2005	N/A
Applicant	CareFusion (Now BD)	Medegen Medical Manufacturing Services (Now BD)	N/A
Model Numbers	72215N 10016073	Various	N/A
Classification Regulation	Same as predicate	21 CFR 880.5440	N/A
Regulation Name	Same as predicate	Intravascular Administration Set	N/A
Device Class	Same as predicate	II	N/A
Product Code	Same as predicate	FPA	N/A
Review Branch	Same as predicate	General Hospital	N/A
Indications for Use	The BD Secondary Set is indicated for continuous or intermittent delivery of IV fluids, medications, including lipids through intravascular routes of administration. The BD Secondary Set may be used with	The Intravascular Administration Set and Extension Set is a device used to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into the patient's artery or vein. The Intravascular	The indications are essentially the same with the exception being the subject device lists specific fluid types and a general patient population. The predicate device does not specify fluid types or

Characteristic	Subject Device: BD Secondary Infusion Sets	Predicate Device: Intravascular Administration and Extension Sets	Equivalence Discussion
	any patient population with consideration given to the procedure being performed and fluids being infused.	Administration Set and Extension Set may incorporate componentry that aid in the prevention of accidental needle sticks.	patient population. The subject device fluids were assessed based on clinical use. Functional testing on the subject device was conducted to demonstrate compatibility with fluid types.
Intended Use	The BD Secondary Infusion Set is intended for the intravascular administration of fluids from a container to a patient's vascular system.	The Intravascular Administration Set and Extension Set is a device used to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into the patient's artery or vein.	The subject device intended use is the same; intended for fluid administration to the patient's vascular system through a needle or catheter.
Drip Chamber	PVC, Acrylonitrile Butadiene Styrene (ABS), Polyethylene	Butadiene Styrene (ABS), Polypropylene, PTFE/PES, PVC	The safety of materials that comprise the finished device was demonstrated by the results of biocompatibility.
Tubing (Non DEHP)	Same as predicate	PVC	The safety of materials that comprise the finished device was demonstrated by the results of biocompatibility.

Characteristic	Subject Device: BD Secondary Infusion Sets	Predicate Device: Intravascular Administration and Extension Sets	Equivalence Discussion
Roller Clamp	Acrylonitrile Butadiene Styrene (ABS)	Material type not listed in predicate 510(k)	Roller clamp is not patient contacting. Verification testing was completed to demonstrate the performance of the roller clamp.
Male Luer Lock	Modified Acrylonitrile Butadiene Styrene (MABS)	Acrylic	The safety of materials that comprise the finished device was demonstrated by the results of biocompatibility.
Male Luer Lock Cap	Polyethylene	Polypropylene	The safety of materials that comprise the finished device was demonstrated by the results of biocompatibility.
Hanger	Same as predicate	HDPE	N/A
Set Length	10016073: 31 inches 72215N: 40 inches	40 inches	Substantially equivalent; the subject and predicate devices have a similar set length.
Priming Volume	10016073: 11 mL 72215N: 13 mL	Not listed in predicate 510(k)	Verification testing was completed for the priming volume.
Drip Rate	10016073: 20/mL 72215N: 15/mL	15/mL and 20/mL	Verification testing was conducted to confirm performance of drip rate.

Characteristic	Subject Device: BD Secondary Infusion Sets	Predicate Device: Intravascular Administration and Extension Sets	Equivalence Discussion
Packaging Type	Perforated Pouch	Peelable Tyvek/Film Pouch	The packaging is not the sterile barrier. The sterile barrier consists of the drip chamber cap and male luer cap. Microbial barrier testing was conducted as part of shelf-life performance testing.
Sterilization Method	Same as predicate	Irradiation	N/A
Sterility Assurance Level	Same as predicate	10^{-6}	N/A
Device Utility	Same as predicate	Disposable, Single use only, Fluid path sterile	N/A
Shelf Life	Same as predicate	3 years	N/A
Device Duration	Up to 7 days (168 hours)	Up to 96 hours	Verification testing was conducted to show performance of the subject device for the intended duration of 7 days (168 hours).
Mode of Fluid Delivery	Same as predicate	Gravity	N/A
Biocompatibility	Same as predicate	Meets ISO 10993	N/A

Safety and Performance Testing

Nonclinical Testing

The BD Secondary Infusion Set 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 Secondary Infusion Set was 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.

- FDA Recognition Number 6-11, 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 6-129, 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 6-447, ISO 8536-4:2019, Infusion equipment for medical use - Part 4: Infusion sets for single use, gravity feed
- ISO 8536-14:2016, Infusion equipment for medical use – Part 14: Clamps and flow regulators for transfusion and infusion equipment without fluid contact
- USP 41, National Formulary 36 (USP), General Chapter <788> Particulate Matter In Injections
- FDA Recognition Number 14-528, 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 14-409, ISO 11137-2:2013, Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose
- FDA Recognition Number 14- 514, ISO 11737-1:2018, Sterilization of health care products -- Microbiological methods -- Part 1: Determination of a population of microorganisms on products
- FDA Recognition Number 14-530, ISO 11607-1:2019, Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems

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 Secondary Infusion Set is categorized as an externally communicating, indirect blood path, prolonged (> 24 hours to 30 days) device in accordance with ISO 10993-1 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." The battery of tests included the following:

- Cytotoxicity (ISO 10993-5, FDA recognition number 2-245)
- Sensitization (ISO 10993-10, FDA recognition number 2-296)
- Irritation or Intracutaneous Activity (ISO 10993-10, FDA recognition number 2-296)
- Acute Systemic Toxicity (ISO 10993-11, FDA recognition number 2-255)
- Sub-acute/ Sub-chronic Toxicity (ISO 10993-11, FDA recognition number 2-255)
- Material Mediated Pyrogenicity (ISO 10993-11, FDA recognition number 2-255)
- Hemocompatibility (ASTM F756, FDA Recognition number 2-250 and ISO 10993-4, FDA recognition number 2-248)

Clinical Data

Not Applicable. There are no clinical data included in this submission.

Conclusion

The information provided in this 510(k) submission, including the non-clinical safety and performing testing, is sufficient to demonstrate substantial equivalence of the BD Secondary Infusion Set to the predicate device. The BD Secondary Infusion Set and its predicate have similar indications for use, the same intended use, and similar technological characteristics. Any differences between the subject and predicate devices are supported by performance data and do not raise new questions of safety and effectiveness.