July 21, 2023

CareFusion
Roya Borazjani
VP Regulatory Affairs, WWIPD
10020 Pacific Mesa Blvd
San Diego, California 92121

Re: K221327
Trade/Device Name: BD Alaris™ Pump Infusion Sets
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: FPA
Dated: June 21, 2023
Received: June 21, 2023

Dear Roya Borazjani:

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.
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)*
K221327

Device Name
BD Alaris™ Pump Infusion Sets

Indications for Use *(Describe)*
The BD Alaris™ Pump Infusion Set is indicated for use by trained healthcare professionals within healthcare facilities through intravenous, intra-arterial and subcutaneous routes for adults, pediatrics and neonates or irrigation of fluid spaces for adults.

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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CareFusion
has joined BD

K221327 - 510(k) Summary

Submitter Information

Company Name:	CareFusion
Company Address:	10020 Pacific Mesa Blvd. San Diego, CA 92121, USA
Name of Contact	Roya Borazjani, Ph.D.
Company Phone:	1-(801)-231-0002
Email:	roya.borazjani@bd.com
Date Prepared:	July 21, 2023

Device Identification

Trade Name:	BD Alaris™ Pump Infusion Sets
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

The BD Alaris™ Pump Infusion Sets are substantially equivalent to the following predicate device:

Predicate Device	Manufacturer	510(k) #	Date Cleared
ALARIS Medical Infusion System Administration Sets	ALARIS Medical Systems, Incorporated (now owned by Becton Dickinson)	K022209	August 6, 2002

Reason for Submission

The reason for this submission is to update the BD Alaris™ Pump Infusion Sets Indications for Use to include applicable routes of administration and patient populations.

Device Description

The BD Alaris™ Pump Infusion Set is designed to interface with the BD Alaris™ Pump Module or to be used for gravity infusion. The BD Alaris™ Pump Infusion Set is a single-use infusion

set that is available in various configurations of the following components: fluid container spike, vent cap, drip chamber, pump segment assembly, roller clamp and/or pinch clamp, SmartSite™ Y-sites, check valve and male luer lock connector. The drip chamber cap located at the proximal end of the infusion set and the male luer lock cap located at the distal end of the infusion set maintain sterility of the fluid path prior to use. The spike located on the proximal end of the drip chamber is inserted into a fluid container. The infusion set is supplied fluid-path sterile using gamma irradiation and is non-pyrogenic.

Intended Use

The BD Alaris™ Pump Infusion Set is for use with the BD Alaris™ Pump Module or gravity flow and is intended for continuous or intermittent delivery of fluids and medications through clinically acceptable routes of administration.

Indication for Use

The BD Alaris™ Pump Infusion Set is indicated for use by trained healthcare professionals within healthcare facilities through intravenous, intra-arterial and subcutaneous routes for adults, pediatrics and neonates or irrigation of fluid spaces for adults.

Technological Characteristics

Technological characteristics of the subject device are substantially equivalent to the predicate device. The subject BD Alaris™ Pump Infusion Sets achieve their intended use based on the same technology and principles of operation as the predicate ALARIS Medical Infusion System Administration Sets. A comparison of the subject and predicate device technological characteristics is provided in the Table 5-1.

Substantial Equivalence Table and Discussion

The BD Alaris™ Pump Infusion Sets are substantially equivalent to the predicate device in terms of intended use and technological characteristics. Table 5-1 below provides a comparison of the intended use and key technological features.

Table 5-1. ***Comparison of the BD Alaris™ Pump Infusion Sets to the Predicate Device***

Parameters	**SUBJECT DEVICE** **BD Alaris™ Pump Infusion Sets** **(K221327)**	**PREDICATE DEVICE** **ALARIS Medical Infusion System Administration Sets** **(K022209)**	**Comparison**
Manufacturer	CareFusion	CareFusion (formerly ALARIS Medical Systems)	Same
Indications for Use	The BD Alaris™ Pump Infusion Set is indicated for use by trained healthcare professionals within healthcare facilities through intravenous, intra-arterial and subcutaneous routes for adults, pediatrics and neonates or irrigation of fluid spaces for adults.	The following ALARIS Medical Infusion Systems 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, medications, blood and blood products: • IVAC Signature Edition Infusion Pumps and Administration Sets • IVAC MedSystem III Multi-Channel InfusionPump and IVAC MedSystem III Multi-Channel Infusion Pump with DLE and Administration Sets • IMED Gemini Infusion Pumps/Controllers and Administration Sets • ALARIS Medical Medley Medication Safety System and Administration Sets • IVAC, IMED, and ALARIS Gravity, Extension, Components, and Secondary Administration Sets	The subject device has the same intended use as the predicate device. Both the subject device and predicate device are intended to be used with BD Alaris infusion pumps. Updates to specify patient populations as adults, pediatrics, and neonates
Contact Category Per ISO 10993-1	Externally communicating, indirect blood path and indirect tissue contact, prolonged exposure (>24 hours to 30 days); Surface contacting, intact skin (gloved user), and limited duration (≤ 24 hours).	Same	Same

Parameters	SUBJECT DEVICE BD Alaris™ Pump Infusion Sets (K221327)	PREDICATE DEVICE ALARIS Medical Infusion System Administration Sets (K022209)	Comparison
Pump Compatibility	BD Alaris™ Pump Module	Same	Same
Method of Administration	Gravity or Pump	Same	Same
Use Environment	Healthcare Facility	Same	Same
Set Lengths	105 - 126 inches	Same	Same
Set Inner Diameter (ID)	0.118 in./ 0.107 in	0.118 in./ 0.107 in	Same
Set Outer Diameter (OD)	0.164 in / 0.145 in	0.164 in / 0.145 in	Same
Priming Volume	2420-0007: 25 mL 2426-0007: 26 mL 2207-0007: 27 mL 10942011: 23 mL 11484001: 23 mL	2420-0007: 25 mL 2426-0007: 26 mL 2207-0007: 27 mL 10942011: 23 mL 11484001: 23 mL	Same
Drip Chamber	Polyvinyl Chloride, Acrylonitrile Butadiene Styrene, Polyethylene, and Acrylic Copolymer	Polyvinyl Chloride	Different; safety of materials that comprise the finished device was demonstrated by the passing results of ISO 10993 biocompatibility testing
Tubing	Polyvinyl Chloride	Same	Same
Check Valve	Silicone Rubber and Acrylic	Acrylonitrile Butadiene Styrene and Silicone	Different; safety of materials that comprise the finished device was demonstrated by the passing results of ISO 10993 biocompatibility testing

Parameters	SUBJECT DEVICE BD Alaris™ Pump Infusion Sets (K221327)	PREDICATE DEVICE ALARIS Medical Infusion System Administration Sets (K022209)	Comparison
SmartSite Valve	Acrylic, Polyurethane, Silicone Rubber, Polyphenylmethyldimethylsiloxane, and Fluorosilicone Fluid	Same	Same
Pump Segment	Acrylonitrile Butadiene Styrene, Polycarbonate, Silicone Rubber, Polyethylene, and Silicone	Polyvinyl Chloride, Silicone, Acrylic Polymer, Acrylonitrile Butadiene Styrene	Different; safety of materials that comprise the finished device was demonstrated by the passing results of ISO 10993 biocompatibility testing
Pinch Clamp	Acrylonitrile Butadiene Styrene	Not Applicable (slide clamp)	Same
Roller Clamp	Acrylonitrile Butadiene Styrene	Acrylonitrile Butadiene Styrene and Nylon	Different; safety of materials that comprise the finished device was demonstrated by the passing results of ISO 10993 biocompatibility testing
Male Luer Lock	Polyethylene	Acrylonitrile Butadiene Styrene	Different; safety of materials that comprise the finished device was demonstrated by the passing results of ISO 10993 biocompatibility testing
Male Luer Cap	Polyethylene	Same	Same
Tubing Adapter	Acrylonitrile Butadiene Styrene	Same	Same
Bonding Agents	Cyclohexanone and/or Cyclohexanone /Methyl Ethyl Ketone	Same	Same
Non-DEHP	Yes	No	Different; safety of materials that comprise the finished device was demonstrated by the passing results of ISO 10993 biocompatibility testing
Non-Pyrogenic	Yes	Same	Same
Device Usage	Single Use	Same	Same

Parameters	SUBJECT DEVICE BD Alaris™ Pump Infusion Sets (K221327)	PREDICATE DEVICE ALARIS Medical Infusion System Administration Sets (K022209)	Comparison
Sterility	Gamma Radiation	Same	Same
Shelf Life	3 years	Same	Same
Packaging	Individually Packaged	Same	Same

Non-Clinical Data

Design verification testing was performed to demonstrate that the subject devices are equivalent to the predicate device. All test results met their acceptance criteria and support that the BD Alaris™ Pump Infusion Sets are as safe and effective as the predicate device and are appropriately designed for their intended use.

Performance testing completed on the subject device were limited to those tests required to support a substantial equivalence determination between the subject and predicate devices.

Human factors testing was performed in according to the following FDA recognized performance standards and guidelines:

- IEC 62366-1:2015, Medical devices—Part 1: Application of usability engineering to medical devices.
- IEC 62366-2:2016, Medical devices—Part 2: Guidance on the application of usability engineering to medical devices
- ANSI/AAMI HE75:2009/ (R 2018), Human factors engineering Design of medical devices.
- AAMI TIR 101:2021 – Fluid Delivery Performance Testing for Infusion Pumps.
- AAMI TIR17:2008 – Compatibility of materials subject to sterilization.
- IEC 60601-1-6: 2013 Third Edition, Medical Electrical Equipment – General Requirements for Basic Safety and Essential Performance – Collateral Standard: Usability
- Guidance for Industry and FDA staff; Intravascular Administration Sets Premarket Notification Submissions [510(k)], July 11, 2008
- Guidance for Industry and Food and Drug Administration Staff; Applying Human Factors and Usability Engineering to Medical Devices, February 3, 2016
- Guidance for Industry and FDA staff; Infusion Pumps Total Product Life Cycle, December 2, 2014

The following functional, bench and system testing have been performed:

- Gravity Flow Rate utilizing ISO 8536-4 Infusion equipment for medical use – Part 4: Infusion sets for single use, gravity feed
- Microbial Ingress per FDA guidance document, Intravascular Administration Sets Premarket Notification Submissions [510(k)] Aerosol Challenge per internal protocol.
- Human Factors/Usability Engineering per standards listed above
- Flow Rate Accuracy
    - AAMI TIR101:2021 Fluid delivery performance testing for infusion pumps
    - FDA guidance document, Infusion Pumps Total Product Life Cycle

- Bolus Accuracy
    - AAMI TIR101:2021 Fluid delivery performance testing for infusion pumps
    - FDA guidance document, Infusion Pumps Total Product Life Cycle
- Air-in-Line
- Upstream Occlusion Time-to-Alarm
- Post Occlusion Bolus & Downstream Occlusion Time to Alarm

Biocompatibility

A biocompatibility evaluation was conducted in accordance with *ISO 10993-1:2018, Biological evaluation of medical devices – Part 1: Biological evaluation and testing within a risk management process*, FDA's guidance document, *Use of ISO 10993-1:2018, "Biological evaluation of medical devices – Part 1: Biological evaluation and testing within a risk management process"* (September 4, 2020), and FDA guidance document, *Premarket Assessment of Pediatric Medical Devices* (March 24, 2014). Contact classification per ISO 10993-1 is as follows:

- Externally communicating, blood path indirect, and prolonged exposure (>24 hours to 30 days);
- Externally communicating, tissue contact (indirect), and prolonged exposure (>24 hours to 30 days); and
- Surface contacting, intact skin (gloved user), and limited duration (≤ 24 hours).

A Biological and Chemical Risk Assessment for BD Alaris™ Pump Infusion Sets was conducted, and the following tests were addressed:

- Cytotoxicity per ISO 10993-5:2009, Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
- Irritation per ISO 10993-23:2021, Biological evaluation of medical devices – Part 23: Tests for irritation
- Sensitization per ISO 10993-10:2021 Biological evaluation of medical devices – Part 10: Tests for skin sensitization
- Material Mediated Pyrogenicity per ISO 10993-11:2017, Biological evaluation of medical devices – Part 11: Tests for systemic toxicity
- System Toxicity per ISO 10993-11:2017, Biological evaluation of medical devices – Part 11: Tests for systemic toxicity
- Hemolysis per ISO 10993-4:2017, Biological evaluation of medical devices – Part 4: Interactions with blood
- Genotoxicity per ISO 10993-3:2014, Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
- Particulates per USP <788> Particulate matter in injections

The subject BD Alaris™ Pump Infusion Sets met the acceptance criteria for all functional, microbial ingress, sterility, biocompatibility, and other performance criteria, including the essential system performance, which verify the sets to be substantially equivalent to the predicate

devices. Results of the testing demonstrate that there are no new issues of safety and efficacy that are raised with the BD Alaris™ Pump Infusion Sets. A risk assessment was completed, and no new or additional risks were identified.

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/AMD 1:2013 "Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices — Amendment 1"
- 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 (2015)
- ANSI/AAMI ST72:2011 R:2016 – Bacterial endotoxins – Test methods, routine monitoring and alternatives to batch testing.

Shelf-Life:

- ASTM D642-15 Standard Test Method for Determining Compressive RESISTANCE OF Shipping Containers, Components, and Unit Loads
- ASTM D4169-16 Standard Practice for Performance Testing of Shipping Containers and Systems
- ASTM D4332-14 Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing
- ASTM D4728-06 Standard Test Method for Random Vibration Testing of Shipping Containers
- ISO 11607-1 First Edition 2006-04-15 Packaging for Terminally Sterilized Medical Devices – Part 1: Requirements for Materials, Sterile Barrier Systems And Packaging Systems [Including: Amendment 1 (2014)]; and
- ISO 11607-2 First Edition 2006-04-15 Packaging for Terminally Sterilized Medical Devices – Part 2: Validation Requirements for Forming, Sealing and Assembly Processes [Including: Amendment 1 (2014)].

The subject BD Alaris™ Pump Infusion Sets meet all the acceptance criteria for all functional, microbial ingress, sterility, biocompatibility, and other performance criteria which verify the sets to be substantially equivalent to the predicate devices. Results of the testing demonstrate that there are no new issues of safety and efficacy that are raised with the BD Alaris™ Pump Infusion

Sets. A risk assessment was completed, and no new or additional risks were identified.

Clinical Data

There are no clinical data included in this submission.

Summary of Substantial Equivalence

The information provided above supports the BD Alaris™ Pump Infusion Sets substantial equivalence to the identified predicate device. Substantial equivalence has been demonstrated through a comparison of intended use, design, and technological characteristics, as well as performance evaluations. The BD Alaris™ Pump Infusion Sets are as safe and effective as the predicate device.