October 30, 2025

CareFusion (BD)
Michael Pacelli
Senior Regulatory Manager
10200 Pacific Mesa Blvd.
San Diego, California 92121

Re: K250325
Trade/Device Name: BD Alaris Pump Infusion Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular administration set
Regulatory Class: Class II
Product Code: FPA
Dated: September 29, 2025
Received: September 29, 2025

Dear Michael Pacelli:

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.

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.

Submission Number *(if known)*

K250325

Device Name

BD Alaris Pump Infusion Set

Indications for Use *(Describe)*

The BD Alaris™ Pump Infusion Set is indicated for pump use by experienced healthcare professionals within healthcare facilities through intravenous, intra-arterial and subcutaneous routes for adults, pediatrics and neonates or irrigation of fluid spaces for adults. Based on clinical discretion these sets can be used for temporary intravenous gravity infusion.

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."

K250325 - 510(k) SUMMARY (21 CFR §807.92)

BD Alaris™ Pump Infusion Sets

I. Submitter Information

Submitter Name:	CareFusion (Now BD)
Submitter Address:	10020 Pacific Mesa Blvd San Diego, CA 92121, USA
Contact Person:	Michael Pacelli Senior Regulatory Manager
Email Address:	michael.pacelli@bd.com
Phone Number:	(551) 269-3879
Date of Preparation:	October 30, 2025

II. Device Identification

510(k) Number:	K250325
Trade Name:	BD Alaris™ Pump Infusion Set
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

III. Predicate Device

510(k) Number:	K221327
Trade Name:	BD Alaris Pump Infusion Set
Regulation Name:	Intravascular Administration Set
Classification Panel:	General Hospital
Regulation Number:	21 CFR 880.5440
Regulatory Class:	Class II
Product Code:	FPA
Manufacturer:	CareFusion

V. Device Description

The subject BD Alaris™ Pump Infusion Set is a single-use infusion set incorporating a spiked drip chamber on the proximal end, which is inserted into a fluid container, and a male luer lock connector on the distal end which connects to a patient's access device. The spike cap and the male luer lock cap

maintain sterility of the fluid path prior to use. The BD Alaris™ Pump Infusion Set is supplied fluid-path sterile using gamma irradiation and is non-pyrogenic. The subject BD Alaris™ Pump Infusion Set incorporates a pump segment designed to interface with the BD Alaris™ Pump Module for administration of fluids, medications, and parenteral nutrition through clinically acceptable routes of administration.

The BD Alaris™ Pump Infusion Set is available in six (6) configurations incorporating variations of the following components: roller clamp, pinch clamp, slide clamp, SmartSite™ Y-site(s), back check valve, and inline filter.

VI. Indications for Use

The BD Alaris™ Pump Infusion Set is indicated for pump use by experienced healthcare professionals within healthcare facilities through intravenous, intra-arterial and subcutaneous routes for adults, pediatrics and neonates or irrigation of fluid spaces for adults. Based on clinical discretion these sets can be used for temporary intravenous gravity infusion.

VII. Technological Characteristics and Substantial Equivalence

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

Table 1. Subject and Predicate Device Comparison

Characteristic	SUBJECT DEVICE BD Alaris™ Pump Infusion Set K250325	PREDICATE DEVICE BD Alaris™ Pump Infusion Set K221327	Discussion of Differences
Manufacturer	CareFusion (Now BD)	CareFusion (Now BD)	Same
Intended Use	The BD Alaris™ Pump Infusion Set is for use with the BD Alaris™ Pump Module and is intended for continuous or intermittent delivery of fluids, medications and parenteral nutrition through clinically acceptable routes of administration.	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.	Same
Indications for Use	The BD Alaris™ Pump Infusion Set is indicated for pump use by experienced healthcare professionals within healthcare facilities through intravenous, intra-arterial and subcutaneous routes for adults, pediatrics and neonates or irrigation of fluid spaces for adults. Based on clinical discretion these sets can be used for temporary intravenous gravity infusion.	The BD Alaris™ Pump Infusion Set is indicated for pump use by experienced healthcare professionals within healthcare facilities through intravenous, intra-arterial and subcutaneous routes for adults, pediatrics and neonates or irrigation of fluid spaces for adults.	Same
Contact Category per ISO 10993-1	• Externally communicating, indirect blood path and indirect tissue contact, prolonged exposure (>24 hours to 30 days)	• Externally communicating, indirect blood path and indirect tissue contact, prolonged exposure (>24 hours to 30 days)	Same

Characteristic	SUBJECT DEVICE BD Alaris™ Pump Infusion Set K250325	PREDICATE DEVICE BD Alaris™ Pump Infusion Set K221327	Discussion of Differences
	• Surface contacting, intact skin (gloved user), limited duration (≤24 hours)	• Surface contacting, intact skin (gloved user), limited duration (≤24 hours)	
Method of Administration / Pump Compatibility	BD Alaris™ Pump Module or temporary intravenous gravity based on clinical discretion.	BD Alaris™ Pump Module or gravity.	Same
Set Length	~47 – ~136 inches	~105 – ~126 inches	Different The subject device SKUs have different total lengths as compared to the predicate device. Verification and validation testing has demonstrated differences in set performance with the pump. Labeling mitigations identify the deviations in performance and the residual risks are determined to be acceptable through a benefit risk assessment.
	388366 (11171447): ~126” 11426965: ~136” 388365 (2202-0007): ~122” 388163 (10561554): ~126” 2432-0007: ~117” 388364 (2204-0007): ~47”	2420-0007: ~117” 2426-0007: ~126” 2207-0007: ~118” 10942011: ~109” 11484001: ~105”	

Characteristic	SUBJECT DEVICE BD Alaris™ Pump Infusion Set K250325	PREDICATE DEVICE BD Alaris™ Pump Infusion Set K221327	Discussion of Differences
Set Tubing Dimensions	Clear PVC Tubing: 0.145 OD x 0.107" ID Clear PVC Tubing: 0.164" OD x 0.118" ID Pump Segment Clear Silicone Tubing: 0.129"-0.132" ID x 0.029"-0.031" wall thickness	Clear PVC Tubing: 0.145" x 0.107" Clear PVC Tubing: 0.164" x 0.118" Pump Segment Clear Silicone Tubing: 0.129"-0.132" ID x 0.029"-0.031" wall thickness	Same
Priming Volume	~14 mL – ~28 mL	~23 mL – ~27 mL	Different The subject devices have different priming volumes than the predicate. This difference does not raise new questions of safety and effectiveness as confirmed through the data provided in this submission.
	388366 (11171447): ~26 mL 11426965: ~28 mL 388365 (2202-0007): ~27 mL 388163 (10561554): ~26 mL 2432-0007: ~28 mL 388364 (2204-0007): ~14 mL	10942011: ~23 mL 1148400: ~23 mL 2420-0007: ~25 mL 2426-0007: ~26 mL 2207-0007: ~27 mL	
Drip Chamber (Vented / Non-Vented)	<u>Drop Size</u> 20 Drop 20 Drop w/ 15 Micron Filter <u>Sub-Component Materials</u> *Spike Cap*: Low Density Polyethylene (LDPE)	<u>Drop Size</u> 20 Drop <u>Sub-Component Materials</u> *Spike Cap*: LDPE	Different The subject devices incorporate additional componentry compared to the predicate device. Verification and validation testing demonstrates the subject device performs as

Characteristic	SUBJECT DEVICE BD Alaris™ Pump Infusion Set K250325	PREDICATE DEVICE BD Alaris™ Pump Infusion Set K221327	Discussion of Differences
	Spike: Acrylonitrile Butadiene Styrene (ABS) + White Colorant *Air Filter Housing:* High Density Polyethylene (HDPE) *Air Filter Media:* Acrylic Copolymer *Body:* Polyvinyl Chloride (PVC) + TOTM Plasticizer *15 Micron Filter Housing (filtered drip chambers only)*: ABS + White Colorant *15 Micron Filter Membrane (filtered drip chambers only):* Nylon	*Spike:* ABS + White Colorant *Air Filter Housing:* HDPE *Air Filter Media:* Acrylic Copolymer *Body:* Polyvinyl Chloride (PVC) + TOTM Plasticizer	intended and that these technological differences do not raise new questions of safety and effectiveness.
Back Check Valve	*Housing Inlet*: Acrylic + titanium dioxide *Housing Outlet:* Acrylic Multipolymer *Silicone Disc:* Silicone Rubber + Red Colorant	*Housing Inlet:* Acrylic + titanium dioxide *Housing Outlet:* Acrylic Multipolymer *Silicone Disc:* Silicone Rubber + Red Colorant	Same
SmartSite™ Y-Site	Number of SmartSite™ Y-sites: 0, 3, or 5 *Y-Body*: Acrylic-Based copolymer *Female Luer Adapter:* Polyurethane + White Colorant	Number of SmartSite™ Y-sites: 0, 1, 2, or 3 *Y-Body*: Acrylic-Based copolymer *Female Luer Adapter:* Polyurethane + White Colorant	Similar Subject device 11426965 incorporates five (5) SmartSite™ Y-sites as compared to the predicate device which has a highest

Characteristic	SUBJECT DEVICE BD Alaris™ Pump Infusion Set K250325	PREDICATE DEVICE BD Alaris™ Pump Infusion Set K221327	Discussion of Differences
	SmartSite Piston: Silicone Rubber + Blue Colorant *Piston Lubricant:* Silicone Fluid and Fluorosilicone Fluid	*SmartSite Piston:* Silicone Rubber + Blue Colorant *Piston Lubricant:* Silicone Fluid and Fluorosilicone Fluid	total of three (3). Verification testing including system-level testing with the BD Alaris™ Pump Module was completed to demonstrate performance of the subject device does not raise different questions of safety and effectiveness.
Pump Segment	*Upper Fitment*: ABS + Blue Colorant *Ring Retainer:* Polycarbonate + Blue Colorant *Silicone Tubing:* Platinum Cured Silicone Rubber *Lower Fitment:* Polycarbonate + Blue Colorant *Safety Clamp (Slide Clamp):* HDPE *Safety Clamp Lubricant:* Silicone *Stiffener:* LDPE + Blue Colorant	*Upper Fitment*: ABS + Blue Colorant *Ring Retainer:* Polycarbonate + Blue Colorant *Silicone Tubing:* Platinum Cured Silicone Rubber *Lower Fitment:* Polycarbonate + Blue Colorant *Safety Clamp (Slide Clamp):* HDPE *Safety Clamp Lubricant:* Silicone *Stiffener:* LDPE + Blue Colorant	Same
Tubing	PVC + DOA Plasticizer	PVC + DOA Plasticizer	Same

Characteristic	SUBJECT DEVICE BD Alaris™ Pump Infusion Set K250325	PREDICATE DEVICE BD Alaris™ Pump Infusion Set K221327	Discussion of Differences
Tubing Adapter	Methyl Methacrylate ABS (MABS)	MABS	Same
Slide Clamp	HDPE + Blue Colorant	N/A	Different Verification and validation testing was completed to demonstrate this technological difference does not raise new questions of safety and effectiveness.
Roller Clamp	Acrylonitrile Butadiene Styrene (ABS) + White Colorant	Acrylonitrile Butadiene Styrene (ABS) + White Colorant	Same
Pinch Clamp	ABS	ABS	Same
Male Luer Lock with Non-Vented Cap	*Male Luer Lock:* Methyl Methacrylate ABS (MABS) *Cap:* LDPE	*Male Luer Lock:* MABS *Cap:* LDPE	Same
Filter (Inline)	*Hydrophobic Membrane:* Polytetrafluoroethylene *Hydrophilic Membrane:* Polyethersulfone *Housing:* Acrylic-Based Copolymer	N/A	Different The predicate device does not incorporate an inline filter component.

Characteristic	SUBJECT DEVICE BD Alaris™ Pump Infusion Set K250325	PREDICATE DEVICE BD Alaris™ Pump Infusion Set K221327	Discussion of Differences
			Verification and validation testing has demonstrated differences in set performance with the pump. Labeling mitigations identify the deviations in performance and the residual risks are determined to be acceptable through a benefit risk assessment.
Bonding Agents	10% Cyclohexanone / 90% Methyl Ethyl Ketone Cyclohexanone	10% Cyclohexanone / 90% Methyl Ethyl Ketone Cyclohexanone	Same
Non-DEHP	Yes	Yes	Same
Non-Pyrogenic	Yes	Yes	Same
Sterilization Method	Gamma Radiation	Gamma Radiation	Same
Shelf Life	3 years	3 years	Same
Packaging Type	Individually packaged	Individually packaged	Same

VIII. Performance Testing

Nonclinical Testing

The BD Alaris™ Pump Infusion Set was evaluated via the following nonclinical safety and performance testing to demonstrate that the subject device is substantially equivalent to the predicate device:

Test Performed	Test Method
Particulate Testing	ISO 8536-4:2019 Test Method USP <788> Test Method
Flow Rate – Open and Rigid Container	BD Test Method
Luer Testing	ISO 80369-7:2021 Test Method
Drip Chamber Drop Accuracy	ISO 8536-4:2019 Test Method
Air Leak – 20kPa & 50kPa	ISO 8536-4:2019 Test Method
Air Leak – 200kPa (Vacuum Leak)	ISO 8536-8:2015 Test Method
Bolus 330 kPa Pressure	BD Test Method
Check Valve Blocking, Opening, & Counterflow Pressure	ISO 8536-12:2021 Section A.3 Test Method
Filter Efficiency	ISO 8536-4:2019 Test Method
Flow Stop Activation Force	BD Test Method
Axial Separation Force	BD Test Method
Aerosol Challenge	BD Test Method
SmartSite™ Y-site Needle Free Valve Performance	ISO 594-1:1986 Section 5.2 Test Method ISO 594-1:1986 Section 5.4 Test Method ISO 594-1:1986 & 594-2:1998 Section 5.3 Test Method ISO 594-2:1998 Section 5.5 Test Method ISO 594-2:1998 Section 5.6 Test Method ISO 594-2:1998 Section 5.7 Test Method ISO 594-2:1998 Section 5.8 Test Method BD Test Method
Flow Rate and Bolus Accuracy	AAMI TIR 101:2021
Downstream Occlusion Time-to-Alarm & Post-Occlusion Bolus	BD Test Method
Upstream Occlusion Time-to-Alarm	BD Test Method

Human Factors

Human Factors was performed in accordance with the following FDA-recognized performance standards and guidelines:

- IEC 62366-1 Edition 1.1 2020-06 *Medical Devices – Part 1: Application of usability engineering to medical devices*
- ANSI/AAMI HE75:2009/(R 2018), *Human factors engineering design of medical devices*
- *Guidance for Industry and FDA Staff; Applying Human Factors and Usability Engineering to Medical Devices, February 3, 2016*
- *Draft Guidance for Industry and FDA Staff; Content of Human Factors Information in Medical Device Marketing Submissions*

Biocompatibility

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

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

The following tests were conducted based on this evaluation:

- Cytotoxicity per ISO 10993-5:2009 *Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity*
- Sensitization & Irritation per ISO 10993-10:2021 *Biological evaluation of medical device – Part 10: Tests for skin sensitization*
- Acute Systemic Toxicity per ISO 10993-11:2017 *Biological evaluation of medical device – Part 11: Tests for systemic toxicity*

- Material Mediated Pyrogenicity per ISO 10993-11:2017 *Biological evaluation of medical device – Part 11: Tests for systemic toxicity*
- Sub-acute/ Sub-chronic Toxicity per ISO 10993-11:2017 *Biological evaluation of medical device – Part 11: Tests for systemic toxicity*
- Genotoxicity per ISO 10993-3:2014 *Biological evaluation of medical device – Part 3: Tests for genotoxicity, carcinogenicity, and reproductive toxicity* (2-228)
- Hemocompatibility per ISO 10993-4:2017 *Biological evaluation of medical device – Part 4: Selection of tests for interactions with blood* (2-248)

Microbial Ingress Testing:

Microbial ingress testing 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

XI. Conclusion

The information provided in this submission, including the non-clinical safety and performance testing, demonstrates substantial equivalence of the BD Alaris™ Pump Infusion Set to the predicate device. The BD Alaris™ Pump Infusion Set and its predicate have the same indications for use and intended use, and successful completion of design verification and validation activities demonstrate differences in technological characteristics do not raise new questions of safety and effectiveness. Thus, the BD Alaris™ Pump Infusion Set is substantially equivalent.