July 21, 2023

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

Re: K221319
Trade/Device Name: BD Alaris™ Pump Epidural Infusion Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular administration set
Regulatory Class: Class II
Product Code: PWH
Dated: June 21, 2023
Received: June 21, 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.
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)*
K221319

Device Name
BD Alaris™ Pump Epidural Infusion Set

Indications for Use *(Describe)*
The BD Alaris™ Pump Epidural Infusion Set is indicated for use by trained healthcare professionals within healthcare facilities through the epidural route for adults, pediatrics and neonates.

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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K221319 - 510(K) SUMMARY

Submitter Information

510(k) Submitter:	CareFusion 10020 Pacific Mesa Blvd San Diego, CA 92121, USA
Contact Person:	Paulina Davis Staff Regulatory Affairs Specialist Phone: 714-330-6037 Email Address: Paulina.Davis@BD.com
Date of Summary Preparation:	July 21, 2023

Subject Device Identification

Trade Name:	BD Alaris™ Pump Epidural Infusion Set
Common Name:	Intravascular Administration Set with Neuraxial Connector
Regulation Name:	Intravascular Administration Set
Classification Panel:	General Hospital
Regulation Number:	21 CFR 880.5440
Regulatory Class:	Class II
Product Code:	PWH

Predicate Device Identification

Trade Name:	CADD® Yellow High Volume Administration Set with NRFit™ Connector
510(k) Number:	K172592
510(k) Clearance Date:	May 17, 2018
Regulation Name:	Intravascular Administration Set
Classification Panel:	General Hospital
Regulation Number:	21 CFR 880.5440
Regulatory Class:	Class II
Product Code:	PWH
Manufacturer:	Smiths Medical ASD, Inc.

Reason for Submission

The purpose of this Traditional 510(k) is to obtain clearance to market the BD Alaris™ Pump Epidural Infusion Set which contains an NRFit™ connector. The NRFit™ connector conforms to ISO 80369-6*, Smallbore connectors for liquids and gases in healthcare applications -- Part 6: Connectors for neuraxial applications*. The NRFit™ connector is not compatible with the standard luer connector commonly used for intravenous infusion. The addition of the NRFit™ connector eliminates the risk of misconnection that may result in infusion of medications not intended for an epidural route of administration.

Device Description

The BD Alaris™ Pump Epidural Infusion Set is an administration set consisting primarily of bag spike, vent cap, drip chamber, tubing (including pump segment), safety clamp, roller clamp, male NRFit™ connector, and male NRFit™ cap. The drip chamber cap located at the proximal end of the administration set, and the male NRFit™ cap, located at the distal end of the administration set, maintain sterility of the fluid path prior to usage. The spike located on the proximal end of the drip chamber is inserted into a prepared fluid container. The male NRFit™ connector enables connection of the administration set to a compatible female NRFit™ connector on the patient's epidural catheter. The BD Alaris™ Pump Epidural Infusion Set is intended to interface with the BD Alaris™ Pump Module. The device is supplied fluid-path sterile using gamma irradiation, in a perforated pouch, is non-pyrogenic, and is for single-use only. The device tubing is color-coded with a yellow stripe to signify administration of medication intended for an epidural route of administration. The BD Alaris™ Pump Epidural Infusion Set is not intended for gravity administration. The device is intended for prescription use only. DEHP or natural rubber latex are not part of the material formulation.

The BD Alaris™ Pump Epidural Infusion Set is designed to deliver medications intended for the epidural route of administration. The NRFit™ connector conforms to ISO 80369-6*, Smallbore connectors for liquids and gases in healthcare applications -- Part 6: Connectors for neuraxial applications*. The NRFit™ connector is not compatible with the standard luer connector commonly used for intravenous infusion. The addition of the NRFit™ connector eliminates the risk of misconnection that may result in infusion of medications not intended for an epidural route of administration.

Indication for Use

The BD Alaris™ Pump Epidural Infusion Set is indicated for use by trained healthcare professionals within healthcare facilities through the epidural route for adults, pediatrics and neonates.

Comparison of Technological Characteristics with Predicate Device

Table 5 - 1 compares the BD Alaris™ Pump Epidural Infusion Set to the predicate device, CADD® Yellow High Volume Administration Set with NRFit™ Connector, including the technological characteristics. The results of this comparison demonstrate that the design,

technology, materials and composition of the BD Alaris™ Pump Epidural Infusion Set are substantially equivalent to the predicate CADD® Yellow High Volume Administration Set with NRFit™ Connector.

Table 5 - 1. Comparison of BD Alaris™ Pump Epidural Infusion Set with Predicate CADD® Yellow High Volume Administration Set with NRFit™ Connector

Characteristic	New Device	Predicate Device	Comparison
510(k)	K221319	K172592	N/A
Applicant	CareFusion	Smiths Medical ASD, Inc.	N/A
Trade Name	BD Alaris™ Pump Epidural Infusion Set	CADD® Yellow High Volume Administration Set with NRFit™ Connector	N/A
Model Numbers	NRF2208-0007 NRF2206-0007	21-7684-24	N/A
Classification Regulation	21 CFR 880.5440	21 CFR 880.5440	Same
Regulation Name	Intravascular Administration Set	Intravascular Administration Set	Same
Device Class	II	II	Same
Product Code	PWH	PWH	Same
Indications for Use	The BD Alaris™ Pump Epidural Infusion Set is indicated for use by trained healthcare professionals within healthcare facilities through the epidural route for adults, pediatrics and neonates.	CADD® Yellow High Volume Administration Set with NRFit™ connectors are intended for use only with NRFit™ components for delivery of regional anesthetics or narcotics, excluding subarachnoid / spinal block, and are designed for use with CADD® pumps (see CADD® pump	Epidural administration (the administration route for subject device) is a type of regional administration. 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 infusion pumps and in the same patient populations (adults and pediatrics (also includes neonates).

Characteristic	New Device	Predicate Device	Comparison
		Operator's Manual for compatibility). The intended population is pediatrics and adults.	
Rx or OTC?	Rx	Rx	Same
Utility	Disposable, for Single Use Only	Disposable, Single Use Only	Same
Connection	ISO 80369-6 compliant male connector	ISO 80369-6 compliant male connector	Same
Bag Spike	Acrylonitrile Butadiene Styrene (ABS)	Acrylonitrile butadiene styrene (ABS) – ABS - HI 121H-Natural Granule 9700640000 Colorant: Yellow	Different; safety of materials that comprise the finished device was demonstrated by the passing results of ISO 10993 biocompatibility testing.
Tubing	PVC, silicone	PVC	Different; safety of materials that comprise the finished device was demonstrated by the passing results of ISO 10993 biocompatibility testing.
Male NRFit™ connector	ABS	Polycarbonate – Makrolon RX-1805-013771 Colorant: White	Different; safety of materials that comprise the finished device was demonstrated by the passing results of ISO 10993 biocompatibility testing.
Check valve	No	Yes (part of male NRFit™ connector)	Different; subject device does not have a check-valve as part of the male NRFit™ connector. Check valve is not required because no additional infusion line

Characteristic	New Device	Predicate Device	Comparison
			will be connected for epidural infusions.
Flowstop	Yes (safety clamp)	Yes	Different; Verification testing was completed to demonstrate that the safety clamp performs as intended
Set Length	NRF2208-0007: 117 inches NRF2206-0007: 96 inches	130 inches	Different; system-level performance testing (flow rate and occlusion time-to-alarm) demonstrates the subject device performs as intended.
Priming Volume	NRF2208-0007: 14.4 mL NRF2206-0007: 13 mL	16-23 mL	Different; priming volume of subject devices is calculated based on tubing length and subject device components, and verified through performance testing.
Flow Type	Pump Operated	Pump Operated	Same
Packaging Type	Perforated Pouch	Tyvek Pouch	Different; microbial barrier testing was conducted as part of shelf-life performance to demonstrate the subject device performs as intended
Sterilization	Provided fluid path sterile by gamma irradiation	Provided sterile by ethylene oxide	Different; both Category A sterilization methods. CareFusion has validated that the sterilization method and parameters are adequate to ensure a Sterility Assurance Level (SAL) of 10^{-6}.
Shelf Life	3 years	Unknown	Different; performance testing on accelerated-aged devices demonstrates the subject device performs as

Characteristic	New Device	Predicate Device	Comparison
			intended through its labeled shelf life.

Safety and Performance Testing

The BD Alaris™ Pump Epidural Infusion Set was evaluated via non-clinical safety and performance testing to demonstrate that the device met pre-established acceptance criteria and is substantially equivalent to the predicate device.

The safety and performance testing on the BD Alaris™ Pump Epidural Infusion Set was conducted according to the following FDA recognized and internally recognized consensus standards listed below:

Human Factors

- FDA Recognition Number 5-57, ANSI/AAMI HE75: 2009 (R2013), Human factors engineering- Design of medical devices
- FDA Recognition Number 5-114, IEC 62366-1: Edition 1.0 2015, Medical devices – Part 1: Application of usability engineering to medical devices [Including CORRIGENDUM 1 (2016)]

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

- FDA Recognition Number 6-318, ISO 8536-4: 2010/Amd1: 2013(E), Infusion equipment for medical use - Part 4: Infusion sets for single use, gravity feed [Including: Amendment 1 (2013)]
- FDA Recognition Number 6-358, ISO 8536-8: 2015, Infusion Equipment for Medical Use - Part 8: Infusion Sets for Single Use with Pressure Infusion Apparatus
- FDA Recognition Number 5-121, ISO 80369-1: 2018, Small-bore connectors for liquids and gases in healthcare applications - Part 1: General requirements
- FDA Recognition Number 5-108, ISO 80369-6: 2016, Small bore connectors for liquids and gases in healthcare applications - Part 6: Connectors for neuraxial applications
- FDA Recognition Number 5-97, ISO 80369-20: 2015, Small-bore connectors for liquids and gases in healthcare applications - Part 20: Common test methods
- 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
- EN ISO 14971: 2012, Medical devices - Application of risk management to medical devices

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. Per ISO 10993-1: 2018 the device is categorized as:

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

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

- Cytotoxicity: FDA Recognition Number 2-245, ISO 10994-5: 2009, Biological evaluation of medical devices - Part 5: Tests for In Vitro cytotoxicity
- Sensitization: FDA Recognition Number 2-174, ISO 10993-10: 2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- Irritation or Intracutaneous Activity: FDA Recognition Number 2-291, ISO 10993-23:2021, Biological evaluation of medical devices – Part 23: Tests for irritation
- Acute Systemic Toxicity: FDA Recognition Number 2-255, ISO 10993-11: 2017, Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
- Hemocompatibility: FDA Recognition Number 2-250, ASTM F756-2017, Standard Practice for Assessment of Hemolytic Properties of Materials
- Hemolysis: FDA Recognition Number 2-248, ISO 10993-4: 2017, Biological evaluation of medical devices--Part 4: Selection of tests for interactions with blood
- USP 41, National Formulary 36 (USP), General Chapter <788> Particulate Matter In Injections
- Genotoxicity per ISO 10993-3:2014, Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
- FDA Recognition Number 2-289, ISO 10993-12: 2021, Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
- ISO 10993-17: 2002/(R)2008, Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances
- ISO 10993-18: 2020, Biological evaluation of medical devices – Part 18:

Chemical characterization of materials

- FDA Recognition Number 2-258, ISO 10993-1: 2018, Biological evaluation of medical devices - part 1: Evaluation and testing within a risk management process
- FDA Recognition Number 2-222. ISO 10993-2: 2006, Biological Evaluation of medical devices - Part 2: Animal welfare requirements
- USP 41, National Formulary 36 (USP), General Chapter <151>: 2018, Pyrogen Test (USP Rabbit Test)

Sterilization and Shelf Life/Packaging

- 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 product
- FDA Recognition Number 14-541, ANSI/AAMI ST72: 2019, Bacterial endotoxins – Test methods, routine monitoring, and alternatives to batch testing
- ASTM D4728-17, Random vibration testing of shipping containers
- FDA Recognition Number 14-499, ASTM D4169-16, Standard Practice for Performance Testing of Shipping Containers and Systems
- ASTM D5276-19, Standard Test Method for Drop Test of Loaded Containers by Free Fall
- FDA Recognition Number 14-497, ASTM F1980-16, Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- USP 41, National Formulary 36 (USP), General Chapter <161>: 2018, Medical Devices- Bacterial Endotoxin and Pyrogen Tests
- USP 41, National Formulary 36 (USP), General Chapter <85>:2018, Bacterial Endotoxins Test
- FDA Recognition Number 5-117, ISO 15223-1: 2016, Medical devices - Symbols to be used with medical device labels, labelling, and information to be supplied - Part 1: General requirements

All testing met pre-established acceptance criteria and successfully demonstrated that the device, the BD Alaris™ Pump Epidural Infusion Set, is safe for its intended use and performs as intended. Additionally, the BD Alaris™ Pump Epidural Infusion Set and the predicate CADD® Yellow High Volume Administration Set with NRFit™ Connector were tested to similar standards, including ISO 80369-6, and thus the subject device is considered substantially equivalent to the predicate device.

Clinical Data

There are no clinical data included in this submission.

Conclusion

The information provided in this 510(k) submission, including the non-clinical safety and performance testing, is sufficient to demonstrate substantial equivalence of the BD Alaris™ Pump Epidural Infusion Set to the predicate device. The results of non-clinical safety and performance testing met the pre-established acceptance criteria. The BD Alaris™ Pump Epidural Infusion Set and its predicate have similar indications for use, the same intended use, and similar technological characteristics. The differences in technological characteristics between the subject and predicate devices do not raise new or different questions of safety and effectiveness. Additionally, the information provided demonstrates the subject device is as safe and effective as the predicate device.