July 21, 2023

CareFusion 303 Inc.
Laurie Cartwright
Senior Director, Regulatory Affairs
10020 Pacific Mesa Blvd.
San Diego, California 92121

Re: K211218
Trade/Device Name: BD Alaris System with Guardrails Suite MX v12.1.2
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: FRN, PHC, MEA, CCK
Dated: June 21, 2023
Received: June 21, 2023

Dear Laurie Cartwright:

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,

Juliane C. Lessard -S

Juliane C. Lessard, Ph.D.
Division Director
DHT3C: Drug Delivery and General Hospital Devices & 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)*
K211218

Device Name
BD Alaris System with Guardrails Suite MX v12

Indications for Use *(Describe)*

The BD Alaris System with Guardrails Suite MX is a modular infusion pump and monitoring system for the continuous or intermittent administration of fluids to adult, pediatric, and neonatal patients through clinically accepted routes of administration: intravenous (IV), intra-arterial (IA), subcutaneous, epidural, or irrigation of fluid spaces. See Pediatric*, Neonate**, and Adult Patient Population Tables for the module-specific variations. Administered fluids include pharmaceutical drugs, red blood cells, and other blood components (platelets and fresh frozen plasma) as required for patient therapy. The BD Alaris System is an interoperable system capable of communicating and exchanging data with compatible information technology systems.

The BD Alaris System includes the PC Unit (PCU) and one or more of the following: Pump Module, Syringe Module, End-Tidal CO2 (EtCO2) Module, Auto-ID Module, Patient-Controlled Analgesia (PCA) Module, and associated software applications. The EtCO2 Module is a capnograph that continuously monitors end-tidal carbon dioxide (EtCO2), fractional inspired carbon dioxide (FiCO2), and respiratory rate (RR).

The BD Alaris Pump Module, Syringe Module, and the Alaris PCA Module are indicated for varying patient populations, routes of administration, and infusates.

(See attached additional page)

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.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
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See PRA Statement below.

510(k) Number *(if known)*
K211218

Device Name
BD Alaris System with Guardrails Suite MX v12

Indications for Use *(Describe)*

Attachment

Pediatric* and Neonate Patient Populations**

Module	Route of Administration	Infusates
BD Alaris Pump Module (LVP)	Intravenous	Fluids, pharmaceutical drugs including high-alert medications, chemotherapy, and parenteral nutrition; red blood cells, platelets and fresh frozen plasma.
	Subcutaneous	Fluids and pharmaceutical drugs approved for subcutaneous use.
	Epidural	Pharmaceutical drugs approved for epidural use.
	Intra-arterial	Pharmaceutical drugs approved for intra-arterial use
BD Alaris Syringe Module (SYR)	Intravenous	Fluids, pharmaceutical drugs including high-alert medications, chemotherapy, and parenteral nutrition; red blood cells, platelets and fresh frozen plasma.
	Subcutaneous	Pharmaceutical drugs approved for subcutaneous use.
	Epidural	Pharmaceutical drugs approved for epidural use.
	Intra-arterial	Pharmaceutical drugs approved for intra-arterial use.
Alaris PCA Module (PCA)	Intravenous	Pain management drugs approved for intravenous use
	Epidural	Pain management drugs approved for epidural use

* Pediatric population: One month to 21 years
** Neonate population: Newborns up to one month – includes preterm or term

Adult Patient Population

Module	Route of Administration	Infusates
BD Alaris Pump Module (LVP)	Intravenous	Fluids, pharmaceutical drugs including high-alert medications, chemotherapy, and parenteral nutrition; red blood cells, platelets and fresh frozen plasma.
	Subcutaneous	Fluids and pharmaceutical drugs approved for subcutaneous use.
	Epidural	Pharmaceutical drugs approved for epidural use.
	Intra-arterial	Pharmaceutical drugs approved for intra-arterial use
	Irrigation of fluid spaces	Fluids approved for irrigation.
BD Alaris Syringe Module (SYR)	Intravenous	Pharmaceutical drugs approved for intravenous use.
	Subcutaneous	Pharmaceutical drugs approved for subcutaneous use.
	Epidural	Pharmaceutical drugs approved for epidural use.
	Intra-arterial	Pharmaceutical drugs approved for intra-arterial use.
Alaris PCA Module (PCA)	Intravenous	Pain management drugs approved for intravenous use.
	Subcutaneous	Pain management drugs approved for subcutaneous use.
	Epidural	Pain management drugs approved for epidural use.

510(k) SUMMARY
BD Alaris System with Guardrails Suite MX v12

This summary of 510(k) information is being submitted in accordance with 21 CFR 807.92.

General Information

Submitter Name:	Becton, Dickinson and Company, on behalf of its wholly-owned subsidiary, CareFusion
Address:	10020 Pacific Mesa Blvd. San Diego, CA 92121
Contact Person:	Laurie Cartwright Senior Director, Regulatory Affairs Phone: 858-987-4203 Email: laurie.cartwright@bd.com
Date Prepared:	July 19, 2023

Device Name

Proprietary Name:	BD Alaris System with Guardrails Suite MX v12
Common Name:	Infusion, Pump Infusion Safety Management Software Pump, Infusion, PCA Carbon Dioxide Gas Analyzer
Device Classification:	Class II (classification codes are provided in the following table)

BD Alaris System Product Classification Codes

21 CFR Section	Product Code	Description	Components/Module
880.5725	FRN	Pump, Infusion	Point of Care Unit (PCU)
			Large Volume Pump Module (LVP Module)
			Syringe Module (Syringe Module)
			Auto-ID Module
			System Maintenance (ASM)
	PHC	Infusion safety management software	Calculation Services (CalcServ)
			Systems Manager (SM)
			Infusion Adaptor (IA)
			Guardrails Editor (GRE)
	MEA	Pump, Infusion, PCA	Patient Controlled Analgesia Module (PCA Module)
868.1400	CCK	Carbon dioxide gas analyzer	$EtCO_2$ Module ($EtCO_2$ Module)

Predicate Device

The predicate device is the Alaris System with Guardrails Suite MX cleared under K133532 (August 21, 2014).

Device Description

The BD Alaris System with Guardrails Suite MX v12 is a modular infusion and monitoring system designed to provide accurate, automated infusion of a broad range of drugs and fluids, and to provide monitoring of respiratory parameters. The BD Alaris System with Guardrails Suite MX v12 has three major components:

- System Hardware: a core hardware unit with user interface (BD Alaris PC Unit or PCU) and attachable modules each with a distinct function.
- Guardrails Suite MX Software: software applications for support and interaction with the system hardware (BD Alaris System Manager, BD Alaris Guardrails Editor, and BD Alaris System Maintenance).
- Interoperability Software: applications for bi-directional communication between the PCU/attached modules and an electronic medical records (EMR) system. (Care Coordination Engine, Infusion Adapter, and Calculation Services).

The PCU is the core of the BD Alaris System with Guardrails Suite MX v12 and powers, programs, and monitors the attached modules. Modules must be physically connected to the PCU to operate. The connection is made by direct attachment to a PCU or through attachment to a module that is attached to a PCU. The attachment is made using male and female inter-unit interface connectors built into both sides of the PCU and modules.

The attachable modules are dedicated to infusion of fluids/medication, injection of medication, patient-controlled administration of analgesics, monitoring of end-tidal carbon dioxide, and scanning identifications of patient, physician, and infusates into the system.

Each system must include a PCU. The rules for attachment of the modules are as follows:

- The PCU is designed to operate a maximum of four infusion or monitoring modules. Modules added in excess of four are not recognized, with the exception of the Auto-ID Module that can be included as a fifth module.
- Up to four Pump or Syringe Modules may be attached to a PCU at one time
- Only one PCA and one EtCO2 module can be included within the four attached infusion or monitoring modules, since each BD Alaris System v12 is dedicated to a single patient.
- In order to keep the PCU with attached modules well balanced when attached to a pole, it is important to distribute the modules as evenly as possible on both sides of the PCU unit.

The PCU and attachable modules have multiple processors running embedded software. The embedded software provides various functions, such as: bootloader, user interface, networking, sensor monitoring, motor control, data processing, power control, keypad processing, and communication.

Communication occurs within the PCU or modules, and between the PCU and attached modules. Communication between the units is by direct electrical connection through the mechanical supports on each side of the PCU and modules.

The PCU with its attached modules is designed to be configured to communicate and interact with the BD Alaris System with Guardrails Suite MX v12 software applications including software for interoperability with electronic medical records (EMR) systems. Communication between the PCU and the software application is accomplished through either a direct serial connection with the PCU or through a wireless connection with the PCU. If communication with an application is interrupted, the PCU and modules will continue to function as programmed, but clinicians will need to make changes or inputs manually.

It is important to note that interoperability of the BD Alaris System v12 does not include remote control of the BD Alaris System v12 components. The PCU and attached modules cannot be programmed remotely. Only infusion parameters can be prepopulated on the pump using interoperability and these parameters must be manually confirmed by the clinician before they are activated.

Intended Use

The BD Alaris System with Guardrails Suite MX is intended for use by healthcare professionals for the monitoring and controlled delivery of fluids, medications, blood, and blood products into patients.

Indications for Use

The BD Alaris System with Guardrails Suite MX is a modular infusion pump and monitoring system for the continuous or intermittent administration of fluids to adult, pediatric, and neonatal patients through clinically accepted routes of administration: intravenous (IV), intra-arterial (IA), subcutaneous, epidural, or irrigation of fluid spaces. See Pediatric*, Neonate**, and Adult Patient Population Tables for the module-specific variations. Administered fluids include pharmaceutical drugs, red blood cells, and other blood components (platelets and fresh frozen plasma) as required for patient therapy. The BD Alaris System with Guardrails Suite MX is an interoperable system capable of communicating and exchanging data with compatible information technology systems.

The BD Alaris System with Guardrails Suite MX includes the PC Unit (PCU) and one or more of the following: Pump Module, Syringe Module, end-tidal CO_2 ($EtCO_2$) Module, Auto-ID Module, Patient-Controlled Analgesia (PCA) Module, and associated software applications. $EtCO_2$ Module is a capnograph that continuously monitors end-tidal carbon dioxide ($EtCO_2$), fractional inspired carbon dioxide ($FiCO_2$), and respiratory rate (RR).

BD Alaris Pump Module and Syringe Module and the Alaris PCA Module are indicated for varying patient populations, routes of administration, and infusates.

Table 1: Pediatric* and Neonate Patient Populations**

Module	Route of Administration	Infusates
BD Alaris™ Pump Module	**Intravenous**	Fluids, pharmaceutical drugs including high-alert medications, chemotherapy, and parenteral nutrition; red blood cells, platelets and fresh frozen plasma.
	Subcutaneous	Fluids and pharmaceutical drugs approved for subcutaneous use.
	Epidural	Pharmaceutical drugs approved for epidural use.
	Intra-arterial	Pharmaceutical drugs approved for intra-arterial use.
BD Alaris™ Syringe Module	**Intravenous**	Fluids, pharmaceutical drugs including high-alert medications, chemotherapy, and parenteral nutrition; red blood cells, platelets and fresh frozen plasma.
	Subcutaneous	Pharmaceutical drugs approved for subcutaneous use.
	Epidural	Pharmaceutical drugs approved for epidural use.
	Intra-arterial	Pharmaceutical drugs approved for intra-arterial use.
Alaris™ PCA Module	**Intravenous**	Pain management drugs approved for intravenous use.
	Epidural	Pain management drugs approved for epidural use.

*** Pediatric population:** One month to 21 years
**** Neonate population:** Newborns up to one month – includes preterm or term

Table 2: Adult Patient Population

Module	Route of Administration	Infusates
BD Alaris™ Pump Module	**Intravenous**	Fluids, pharmaceutical drugs including high-alert medications, chemotherapy, and parenteral nutrition; red blood cells, platelets and fresh frozen plasma.
	Subcutaneous	Fluids and pharmaceutical drugs approved for subcutaneous use.
	Epidural	Pharmaceutical drugs approved for epidural use.
	Intra-arterial	Pharmaceutical drugs approved for intra-arterial use.
	Irrigation of fluid spaces	Fluids approved for irrigation.
BD Alaris™ Syringe Module	**Intravenous**	Pharmaceutical drugs approved for intravenous use.
	Subcutaneous	Pharmaceutical drugs approved for subcutaneous use.
	Epidural	Pharmaceutical drugs approved for epidural use.
	Intra-arterial	Pharmaceutical drugs approved for intra-arterial use.
Alaris™ PCA Module	**Intravenous**	Pain management drugs approved for intravenous use.
	Subcutaneous	Pain management drugs approved for subcutaneous use.
	Epidural	Pain management drugs approved for epidural use.

Comparison of Technological Characteristics with the Predicate Device

Comparison of the predicate and proposed device technological characteristics demonstrates that the majority of the devices' technological characteristics are the same; the characteristics that are the same include: principle of operation, maximum infusion pressure, programmable flow rate range, weight and dimensions, and power source.

Differences exist relating to flow rate accuracy, post-occlusion bolus volume, ingress protection, storage/transport relative humidity, and operating condition atmospheric pressure:

- Flow rate and post-occlusion bolus volume specifications for the BD Alaris System v12 have been updated to include more defined test conditions aligned with the current state of the art standard for flow rate accuracy (AAMI TIR 101:2021 *Fluid delivery performance testing for infusion pumps*).
- The predicate device had an ingress protection of IPX1 (protected against falling drops of water) whereas the modified BD Alaris System v12 has been demonstrated to meet the higher IPX2 rating (protected against dripping water, tilted at a 15-degree angle).
- Storage/transport relative humidity has been verified to a wider range than that for the predicate device; this change is associated with the wider range of relative humidity that may be experienced during transport.
- The operating atmospheric pressure range for the BD Alaris System v12 has been changed from a range of 525 to 4560 mmHg to a range of 525 to 795 mmHg. It now excludes hyperbaric use, as the System is not indicated for use in a hyperbaric chamber. The narrowed range for operating atmospheric pressure is aligned with its use profile.

The tables on the following pages provide a side-by-side comparison of the subject device to the predicate device, K133532.

Comparison of Indications for Use and Intended Use

<table>
<tr><th>Characteristic</th><th>Predicate Device
K133532 Alaris System with Guardrails Suite MX</th><th>Subject Device
BD Alaris System with Guardrails Suite MX v12</th></tr>
<tr><td>Indications for Use</td><td>The Alaris System with Guardrails Suite MX is intended for use in professional healthcare facilities that utilize infusion devices for the delivery of fluids, medications, blood and blood products. The Alaris System with Guardrails Suite MX is intended to provide trained healthcare caregivers a way to automate the programming of infusion parameters, thereby decreasing the amount of manual steps necessary to enter infusion data. All data entry and validation of infusion parameters is performed by the trained healthcare professional according to a physician's order. The Alaris System with Guardrails Suite MX is an interoperable system capable of communicating and exchanging data accurately, effectively, securely, and consistently with different information technology systems, software applications, and networks, in various settings; and exchanging data such that the clinical or operational purpose and meaning of the data are preserved and unaltered.</td><td>The BD Alaris System with Guardrails Suite MX is a modular infusion pump and monitoring system for the continuous or intermittent administration of fluids to adult, pediatric, and neonatal patients through clinically accepted routes of administration: intravenous (IV), intra-arterial (IA), subcutaneous, epidural, or irrigation of fluid spaces. Refer the Pediatric*, Neonate** and Adult Patient Population tables for the module-specific variations. Administered fluids include pharmaceutical drugs, red blood cells, and other blood components (platelets and fresh frozen plasma) as required for patient therapy. The BD Alaris System is an interoperable system capable of communicating and exchanging data with compatible information technology systems.
The BD Alaris System includes the PC Unit (PCU) and one or more of the following: Pump Module, Syringe Module, end-tidal CO2 (EtCO2) Module, Auto-ID Module, Patient-Controlled Analgesia (PCA) Module, and associated software applications. EtCO2 Module is a capnograph that continuously monitors end-tidal carbon dioxide (EtCO2), fractional inspired carbon dioxide (FiCO2), and respiratory rate (RR).
BD Alaris Pump Module and Syringe Module and the Alaris PCA Module are indicated for varying patient populations, routes of administration, and infusates. Refer to Table below for the module-specific variations.
Pediatric* and Neonate** Patient Population
<table>
<tr><th>Module</th><th>Route of Administration</th><th>Infusates</th></tr>
<tr><td rowspan="4">BD Alaris Pump Module (LVP)</td><td>Intravenous</td><td>Fluids, pharmaceutical drugs including high-alert medications, chemotherapy, and parenteral nutrition; red blood cells, platelets and fresh frozen plasma</td></tr>
<tr><td>Subcutaneous</td><td>Fluids and pharmaceutical drugs approved for subcutaneous use</td></tr>
<tr><td>Epidural</td><td>Pharmaceutical drugs approved for epidural use</td></tr>
<tr><td>Intra-arterial</td><td>Pharmaceutical drugs approved for intra-arterial use</td></tr>
<tr><td rowspan="4">BD Alaris Syringe Module (SYR)</td><td>Intravenous</td><td>Fluids, pharmaceutical drugs including high-alert medications, chemotherapy, and parenteral nutrition; red blood calls, platelets and fresh frozen plasma</td></tr>
<tr><td>Subcutaneous</td><td>Pharmaceutical drugs approved for subcutaneous use</td></tr>
<tr><td>Epidural</td><td>Pharmaceutical drugs approved for epidural use</td></tr>
<tr><td>Intra-arterial</td><td>Pharmaceutical drugs approved for intra-arterial use.</td></tr>
<tr><td rowspan="2">Alaris PCA Module (PCA)</td><td>Intravenous</td><td>Pain management drugs; for example, opioids</td></tr>
<tr><td>Epidural</td><td>Pain management drugs approved for epidural use</td></tr>
</table>
* Pediatric population: One month to 21 years
** Neonate population: Newborns up to one month – includes preterm or term</td></tr>
</table>

<table>
<tr><th>Characteristic</th><th>Predicate Device
K133532 Alaris System with Guardrails Suite MX</th><th>Subject Device
BD Alaris System with Guardrails Suite MX v12</th></tr>
<tr><td></td><td></td><td>Adult Patient Population
<table>
<tr><th>Module</th><th>Route of Administration</th><th>Infusates</th></tr>
<tr><td rowspan="5">BD Alaris Pump Module (LVP)</td><td>Intravenous</td><td>Fluids, pharmaceutical drugs including high-alert medications, chemotherapy, and parenteral nutrition; red blood calls, platelets and fresh frozen plasma</td></tr>
<tr><td>Subcutaneous</td><td>Fluids and pharmaceutical drugs approved for subcutaneous use</td></tr>
<tr><td>Epidural</td><td>Pharmaceutical drugs approved for epidural use</td></tr>
<tr><td>Intra-arterial</td><td>Pharmaceutical drugs approved for intra-arterial use</td></tr>
<tr><td>Irrigation of fluid spaces</td><td>Fluids approved for irrigation</td></tr>
<tr><td rowspan="4">BD Alaris Syringe Module (SYR)</td><td>Intravenous</td><td>Pharmaceutical drugs approved for intravenous use</td></tr>
<tr><td>Subcutaneous</td><td>Pharmaceutical drugs approved for subcutaneous use</td></tr>
<tr><td>Epidural</td><td>Pharmaceutical drugs approved for epidural use</td></tr>
<tr><td>Intra-arterial</td><td>Pharmaceutical drugs approved for intra-arterial use</td></tr>
<tr><td rowspan="3">Alaris PCA Module (PCA)</td><td>Intravenous</td><td>Pain management drugs approved for intravenous use</td></tr>
<tr><td>Subcutaneous</td><td>Pain management drugs approved for subcutaneous use</td></tr>
<tr><td>Epidural</td><td>Pain management drugs approved for epidural use</td></tr>
</table></td></tr>
<tr><td>Contraindications</td><td>None</td><td>The BD Alaris System is contraindicated for enteral route of administration.</td></tr>
<tr><td>Routes of Administration</td><td>Continuous/Bolus, Intermittent, Fluids through clinically acceptable routes of administration such as intravenous (IV), intra-arterial (IA), subcutaneous, epidural, enteral, or irrigation of fluid spaces.</td><td>Continuous or intermittent delivery through clinically acceptable routes of administration such as intravenous (IV), intra-arterial (IA), subcutaneous, epidural, or irrigation of fluid spaces.</td></tr>
<tr><td>Prescription Only or Over the Counter</td><td>Prescription Only</td><td>Prescription Only</td></tr>
<tr><td>Intended Population</td><td>Adult, pediatric, neonate</td><td>Adult, pediatric, neonate</td></tr>
<tr><td>Environment of Use</td><td>Professional Healthcare Environments</td><td>Professional Healthcare Environments</td></tr>
</table>

Comparison of Technological Characteristics

<table>
<tr><th>Characteristic</th><th>Predicate Device
K133532 Alaris System with Guardrails Suite MX</th><th>Subject Device
BD Alaris System with Guardrails Suite MX v12</th></tr>
<tr><td>Principle of Operation</td><td>The PC Unit provides the power source and the common user interface for programming all attached modules, which helps reduce complexity at the point of care. The PC Unit is responsible for all communication to the modules and is the basis for the modular platform that the healthcare facility can build on to customize infusion delivery to meet individual patient needs by adding or subtracting associated modules.
The system utilizes modular electromechanical componentry to infuse fluids, medications, blood, and blood products when used in conjunction with the dedicated infusion sets. Controlled delivery is achieved through the linear peristaltic pumping action of the pumping chamber section of the infusion set.</td><td>The PC Unit provides the power source and the common user interface for programming all attached modules which helps reduce complexity at the point of care. The PC Unit is responsible for all communication to the modules and is the basis for the modular platform that the healthcare facility can build on to customize infusion delivery to meet individual patient needs by adding or subtracting associated modules.
The system utilizes modular electromechanical componentry to infuse fluids, medications, blood and blood products when used in conjunction with the dedicated infusion sets. Controlled delivery is achieved through the linear peristaltic pumping action of the pumping chamber section of the infusion set.</td></tr>
<tr><td>Accuracy</td><td>
<table>
<tr><th>Module</th><th>Accuracy</th><th>Condition</th></tr>
<tr><td rowspan="2">LVP</td><td>± 5% flow rate</td><td>1 to 999 mL/hr</td></tr>
<tr><td>± 5.5% flow rate</td><td>0.1 to 1 mL/hr</td></tr>
<tr><td>SYR</td><td>± 2 % linear travel</td><td>0.01 to 999 mL/hr</td></tr>
<tr><td>PCA</td><td>± 2 % linear travel</td><td>0.1 to 999 mL/hr</td></tr>
<tr><td rowspan="2">EtCO2</td><td>± 2 mmHg CO2 Conc</td><td>0 to 38 mmHg</td></tr>
<tr><td>5% of reading + 8% per mmHg (above 38 mmHg)</td><td>39 to 99 mmHg</td></tr>
</table>
</td><td>
<table>
<tr><th>Module</th><th>Accuracy</th><th>Conditions</th></tr>
<tr><td rowspan="2">Pump (LVP)</td><td>-19% to + 5.5% system flow rate accuracy</td><td>1 to 999 mL/hr</td></tr>
<tr><td>-8 % to + 5.5% system flow rate accuracy</td><td>0.1 to 1 mL/hr</td></tr>
<tr><td rowspan="5">Syringe (SYR)</td><td>± 7% system flow rate accuracy</td><td>≥ 10% of the syringe volume per hour</td></tr>
<tr><td rowspan="2">± 10% system flow rate accuracy</td><td>≥ 0.1 mL/hr (Syringe sizes ≤ 12 mL)</td></tr>
<tr><td>≥ 1 mL/hr (Syringe sizes > 12 mL)</td></tr>
<tr><td rowspan="2">± 20% system flow rate accuracy</td><td>< 0.1 mL/hr (Syringe sizes ≤ 12 mL)</td></tr>
<tr><td>< 1 mL/hr (Syringe sizes > 12 mL)</td></tr>
<tr><td rowspan="3">PCA</td><td>± 7% system flow rate accuracy</td><td>≥ 10% of the syringe volume per hour</td></tr>
<tr><td>± 10% system flow rate accuracy</td><td>≥ 1 mL/hr</td></tr>
<tr><td>± 20% system flow rate accuracy</td><td>< 1 mL/hr</td></tr>
<tr><td rowspan="2">EtCO2</td><td>± 2 mmHg CO2 Conc</td><td>0–38 mmHg</td></tr>
<tr><td>5% of reading + 8% per mmHg (above 38 mmHg)</td><td>39–99 mmHg</td></tr>
</table>
</td></tr>
<tr><td>Maximum Infusion Pressure</td><td>Pump Module: 525 mmHg
Syringe Module:
• Without pressure sensing disc: Approximately 800 mmHg*
• With pressure sensing disc: 1060 mmHg</td><td>Pump Module: 525 mmHg
Syringe Module:
• Without pressure sensing disc: Approximately 800 mmHg*
• With pressure sensing disc: 1060 mmHg</td></tr>
<tr><td>Programmable Flow Rate Range</td><td>Pump and PCA Modules: 0.1–999 ml/hr
Syringe Module: 0.01–999 mL/hr</td><td>Pump and PCA Modules: 0.1–999 ml/hr
Syringe Module: 0.01–999 mL/hr</td></tr>
</table>

* Actual occlusion pressure varies based on syringe size and manufacturer.

<table>
<tr><th>Characteristic</th><th>Predicate Device
K133532 Alaris System with Guardrails Suite MX</th><th>Subject Device
BD Alaris System with Guardrails Suite MX v12</th></tr>
<tr><td>Bolus Accuracy (Pump)</td><td>Not included in predicate submission</td><td><u>Pump Module</u>
<table>
<tr><th>Rate Range (mL/hr)</th><th colspan="2">Bolus Volume Range (mL)</th><th>Accuracy</th></tr>
<tr><td rowspan="2">Full Range (Without Rapid Bolus Feature)</td><td colspan="2">≥ 0.2 mL</td><td>±10%</td></tr>
<tr><td>< 0.2 mL*</td><td>0.2 mL:
0.1 mL:</td><td>±0.02 mL
±0.025 mL</td></tr>
<tr><td rowspan="3">Full Range (With Rapid Bolus Feature)</td><td colspan="2">≥ 1 mL</td><td>±10%</td></tr>
<tr><td colspan="2">≥ 0.6 mL and < 1 mL</td><td>±15%</td></tr>
<tr><td>< 0.6 mL*</td><td>0.6 mL:
0.1 mL:</td><td>±0.06 mL
0 mL to +0.055 mL</td></tr>
</table>
*Recommended minimum bolus volume is ≥ 0.2 mL without rapid bolus feature and ≥ 0.6 ml with rapid bolus feature</td></tr>
<tr><td>Bolus Accuracy (Syringe and PCA Modules)</td><td>Not included in predicate submission</td><td><u>Syringe Module</u>
<table>
<tr><th>Rate Range (mL/hr)</th><th>Bolus Volume Range (mL)</th><th>Accuracy</th></tr>
<tr><td rowspan="2">Full Range</td><td>≥ 0.2 mL</td><td>±10%</td></tr>
<tr><td>< 0.2 mL*</td><td>±20%</td></tr>
</table>
*Recommended minimum bolus volume is ≥ 0.2 mL

<u>PCA Module</u>
<table>
<tr><th>Rate Range (mL/hr)</th><th>Bolus Volume Range (mL)</th><th>Accuracy</th></tr>
<tr><td rowspan="2">Full Range</td><td>≥ 0.2mL</td><td>±10%</td></tr>
<tr><td>< 0.2mL*</td><td>±20%</td></tr>
</table>
*Recommended minimum bolus volume is ≥ 0.2 mL</td></tr>
<tr><td>Post-occlusion Bolus Volume</td><td>Pump Module:
• ≤ 0.3 mL at 50 mmHg pressure setting
• ≤ 0.6 mL at 525 mmHg pressure setting
Syringe and PCA Modules:
• < 1.1 mL at high pressure setting without pressure sensing disc</td><td>Pump Module:
• ≤ 0.3 mL for all pressure settings (under standard operating conditions)
Syringe and PCA Module:
• ≤ 1.0 mL for all pressure settings (under standard operating conditions)</td></tr>
<tr><td>Alarms and Alerts</td><td>The predicate device contains the following categories of audio and visual alarms, errors, and messages.
• Advisory/Message
• Alarm
• Alert
• Audio Characteristics
• Clinical Advisory
• Error
• Maintenance Reminder
• Prompt</td><td>The subject device contains the following categories of audio and visual alarms, errors, and messages.
• Advisory/Message
• Alarm
• Alert
• Audio Characteristics
• Clinical Advisory
• Error
• Maintenance Reminder
• Prompt</td></tr>
</table>

Characteristic	Predicate Device K133532 Alaris System with Guardrails Suite MX	Subject Device BD Alaris System with Guardrails Suite MX v12
Alarm Handler	Alarm conditions are detected by the Sensor/Actuator and Fluid Delivery Subsystem and reported to the Audio/Visual Alarm subsystem, which prioritizes the alarms and ensures proper enunciation utilizing the user interfaces of the PCU and Modules.	Alarm conditions are detected by the Sensor/Actuator and Fluid Delivery Subsystem and reported to the Audio/Visual Alarm subsystem, which prioritizes the alarms and ensures proper enunciation utilizing the user interfaces of the PCU and Modules.
Device Service Life	Not included in predicate submission	7 Years
Weight	28.3 lbs (13 kg) maximum-weight supported configuration	28.3 lbs (13 kg) maximum-weight supported configuration
Dimensions	PCU: 6.9" W x 8.9" H x 9.0" D (including pole clamp) Pump Module: 3.3" W x 8.9" H x 5.5" D Syringe Module: 4.75" W x 15.0" H x 7.5" D PCA Module: 4.75" W x 15.0" H x 7.5" D EtCO2 Module: 3.3" W x 8.9" H x 5.5" D Auto-ID Module: 2.0" W x 7.25" H x 5.0"D	PCU: 9.0" W x 8.9" H x 9.0" D (including pole clamp) Pump Module: 3.3" W x 8.9" H x 5.5" D Syringe Module: 4.75" W x 15.0" H x 7.5" D PCA Module: 4.75" W x 15.0" H x 7.5" D EtCO2 Module: 3.3" W x 8.9" H x 5.5" D Auto-ID Module: 2.0" W x 7.25" H x 5.0" D
Materials Biocompatibility	Not included in predicate submission	Biocompatible
Ingress Protection	IPX1 rated	IPX2 rated
Power Source	Power Requirement: 100–240 VAC, 50/60 Hz, 150 VA MAX Battery Pack: Rechargeable 12 V, 4000 mAh nickel metal hydride battery	Power Requirement: 100–240 VAC, 50/60 Hz, 150 VA MAX Battery Pack: Rechargeable 12 V, 4000 mAh nickel metal hydride battery
Watchdog Timer	Supported	Supported
Real Time Clock	Supported	Supported
Storage/Transport Conditions	Atmospheric Pressure: 375 to 760 mmHg (500–1013 hPa)	Atmospheric Pressure: 375 to 760 mmHg (500–1013 hPa)
	Relative humidity: 5–85% noncondensing	Relative humidity: 5-90% noncondensing
	Temperature: 4°F–140°F (-20°C–60°C)	Temperature: -4°F–140°F (-20°C–60°C)
Operating Conditions	Atmospheric pressure: 525–4560 mmHg (700–6080 hPa)	Atmospheric Pressure: 525 to 795 mmHg (700 - 1060 hPa)
	Relative humidity: 20 – 90% Noncondensing	Relative humidity: 20 – 90% Noncondensing
	Temperature: 41°F – 104°F (5°C–40°C)	Temperature: 41°F – 104°F (5°C–40°C)
Sterilization	Only the infusion sets are provided sterile. The remaining components are provided non-sterile and are not intended to be sterilized.	Only the infusion sets are provided sterile. The remaining components are provided non-sterile and are not intended to be sterilized.
PCA Monitoring Protocol Functionality:		
PCA/Monitoring Protocol	Guardrails parameter	Guardrails parameter
PCA Required Monitoring Modules	The PCA/Monitoring Protocol is based on hospital-configured monitoring limits. The Protocol will not be enabled and will not activate if hospital-determined monitoring modules ($EtCO_2$ or SPO_2) are not attached.	The PCA/Monitoring Protocol is based on hospital-configured monitoring limits. The Protocol will not be enabled and will not activate if $EtCO_2$ module is not attached.
Pause of PCA infusion due to potential unsafe state	Automatic pause when hospital-configured PCA/Monitoring Protocol limits are exceeded. Opioid medications must be programmed, and monitoring modules ($EtCO_2$ or SPO_2) are attached.	Automatic pause when hospital-configured PCA/Monitoring Protocol limits are exceeded. Opioid medications must be programmed and $EtCO_2$ module is attached.

Characteristic	Predicate Device K133532 Alaris System with Guardrails Suite MX	Subject Device BD Alaris System with Guardrails Suite MX v12
PCA Monitoring Protocol Alarms, Errors, Messages, Advisories	When the PCA/Monitoring protocol is enabled and a specific opioid medication is selected during programming, the clinician will receive a pop-up message to attach an appropriate monitoring module as per established hospital protocol. When the PCA Module is paused as a result of patient monitoring limits exceeding hospital-configured PCA/Monitoring Protocol limits, the clinician will be alerted by a high-priority alarm and a visual message.	When the PCA/Monitoring protocol is enabled and a specific opioid medication is selected during programming, the clinician will receive a pop-up message to attach an appropriate monitoring module as per established hospital protocol. When the PCA Module is paused as a result of patient monitoring limits exceeding hospital-configured PCA/Monitoring Protocol limits, the clinician will be alerted by a high-priority alarm and a visual message.
PCA/Monitoring Protocol	Guardrails parameter	Guardrails parameter

Infusion Management System Comparison

Characteristic	Predicate Device K133532 Alaris System with Guardrails Suite MX	Subject Device BD Alaris System with Guardrails Suite MX v12
Technology	Local server	Local server
Pump Data Transmission	WLAN	WLAN
Dashboard (clinical, biomedical, pharmacy)	Available on the hospital health information technology (HIT) network	Available on the hospital health information technology (HIT) network
Autoprogramming	Supports interfaces to a bar code medication administration (BCMA); supports remote IV orders from EMR system (available with connectivity)	Supports interfaces to a bar code medication administration (BCMA); supports remote IV orders from EMR system (available with connectivity)
Drug Libraries	Available; customizable with an editor	Available; customizable with an editor
Drug Library Updates	Available with connectivity	Available with connectivity
Drug Library Validation	Available with Guardrails Suite	Available with Guardrails Suite
Set Usage	The Alaris System is used in conjunction with dedicated infusion sets.	The Alaris System is used in conjunction with dedicated infusion sets.
Dosing Limits	Soft and Hard Limits	Soft and Hard Limits
Dose Error Reduction	Alaris Guardrails	Alaris Guardrails

Summary of Non-Clinical Testing

Verification and validation testing was completed in support of this premarket notification. The following table provides a summary of the testing:

Test/Analysis	Module
Accuracy	
Flow Rate Accuracy	
Flow Rate Accuracy (SOC and AAMI TIR 101 Compliance)	LVP, SYR, PCA
Flow Rate Accuracy (Non-SOC)	LVP, SYR, PCA
Bolus Accuracy	
Bolus Accuracy (SOC and AAMI TIR 101 Compliance)	LVP, SYR, PCA
Bolus Accuracy (Non-SOC)	LVP, SYR, PCA
Bolus After Set Up - Volume on Door Closure (SOC)	LVP
Bolus Volume, Post-Occlusion (SOC)	LVP, SYR, PCA
Bolus Volume, Post-Occlusion (Non-SOC)	LVP, SYR, PCA
Bolus Volume, Post-Occlusion (SOC + High Pressure)	PCA
Syringe Accuracy	
Syringe Instrument Accuracy (SOC)	SYR, PCA
Pressure Accuracy	SYR, PCA
Deliverable Volume	SYR, PCA
Visually Verifying Syringe Volume	SYR, PCA
Critical Volume Accuracy (SOC)	LVP, SYR
Loading and Flow	
Set Misload	LVP
Syringe Loading	PCA
Syringe Misload	SYR, PCA
Free Flow Protection	LVP
Retrograde Flow	LVP
Anti-Siphon feature Infusion Sets	SYR, PCA
Sympathetic Flow	LVP
Blood Set Test Without Nuisance Occlusion Alarms	LVP
Mechanical Blood Compatibility Test	LVP, SYR
Occlusion Detection	
Occlusion Time-to-Alarm (SOC)	LVP, SYR, PCA
Occlusion Time-to-Alarm (Non-SOC)	LVP, SYR, PCA
Partial Upstream Occlusion Detection	LVP
Midstream Occlusion (Stuck Silicone Tubing) Detection	LVP
Upstream and Downstream Occlusion Time-to-Alarm with Aged Sets	LVP
Air-in-Line Detection	
Single Air Bolus (AIL)	LVP
Accumulated Air-in-Line (SOC)	LVP
Air-in-Line Detection (Non-SOC)	LVP
Air-In-Line (AIL) Engineering Analysis	LVP

Test/Analysis	Module
Alarms	
Alarm and Backup Alarm Test	PCU
Alarm Ability Upon Watchdog Timeout	PCU
Fixed Volume Alarm	PCU
Low Battery Alarm	PCU
Visual Alarm Flash Rate	PCU
Loudness Test	PCU, LVP, SYR, PCA
Battery	
AC to Battery Switchover Test	PCU
Battery Runtime Test	PCU
Battery Storage	PCU
Battery Physical Requirement Inspection Test	PCU
Automatically Condition Battery Analysis	PCU
Mechanical	
Securing PCA Module Engineering Analysis/Report	PCA
Modules Attachment and Removal Inspection Test	PCU, LVP, SYR, PCA, $EtCO_2$
Handle Strength Test	PCU
Pole Clamp Inspection Test	PCU
Minimizing Inadvertent Dislodgement Inspection Test	SYR, PCA
Door and Latch Mechanism Interaction with Adjacent Modules Test	LVP
Service Life Testing (SLT) Engineering Analysis	PCU, LVP, SYR, PCA
Service Life Study Plan Test	PCU, LVP, SYR
Gunk Test	IUI, PCU, LVP, SYR, PCA, $EtCO_2$
Door Gunk Test	LVP
Inspection-Communications Connector Connect/Disconnect & System Power	PCU, LVP, SYR, PCA, Auto-ID
Carrying/Door Handle and Project Tamper Resistant Key Test	PCU
Disposables Interaction with LVP Door and Latch Mechanism Inspection	LVP, $EtCO_2$
Dose Request Cord Inspection Test	PCA
Spallation Test (SOC)	LVP
Push Test	PCU, LVP, SYR, PCA, Auto-ID
Maximum System Weight, Modules Size and Weight	PCU, LVP, SYR, PCA, EtCO2, Auto-ID
Displays	
Display Viewability Test	PCU, LVP, SYR, PCA, $EtCO_2$
Module Channel Display Engineering Analysis	PCU, LVP, SYR, PCA, $EtCO_2$
Operating in Sunlight and Photo Flash Test	PCU, LVP, SYR, PCA, Auto-ID
Segment Display Replacement	LVP, PCA, SYR, EtCO2
Packaging Test	PCU, LVP, SYR, PCA, $EtCO_2$
Cleaning and Disinfection	
Cleaning and Disinfection	PCU, LVP, SYR, PCA, $EtCO_2$
Environmental Operating Parameters	
Storage Temperature and Humidity Tests	PCU, LVP, SYR, PCA, $EtCO_2$
Storage Pressure Test	PCU, LVP, SYR, PCA, $EtCO_2$
Operating Pressure Test	PCU, LVP, SYR, PCA, $EtCO_2$
Keypad with Gasket Storage Temperature and Humidity Test	PCU
Operating on Different Surfaces	PCU, LVP, SYR, PCA, $EtCO_2$
Accuracy after Operation on Treadmill and Elevator Threshold	LVP, SYR, PCA, $EtCO_2$

Test/Analysis	Module
Stress Test	
Drop Test	PCU, LVP, SYR, PCA, $EtCO_2$
Shock and Vibration Test	PCU, LVP, SYR, PCA, $EtCO_2$
Pressure Withstand Test	LVP
Fluid Ingress	
IPX2 and Spillage Test	PCU, LVP, SYR, PCA, $EtCO_2$
Spillage Test	Auto-ID
$EtCO_2$	
Leak Down	$EtCO_2$
Exhaust Port	$EtCO_2$
Auto Zero Engineering Analysis	$EtCO_2$
Auto Zero per ISO 80601-2-55 Engineering Analysis	$EtCO_2$
Respiratory Rate Accuracy Engineering Analysis	$EtCO_2$
Measurement Accuracy Engineering Analysis	$EtCO_2$
Power Supply Engineering Analysis	PCU
Keyboard	
Keypad Press and Audio Verification	PCU, LVP, SYR, PCA
Vented Keypad Analysis	PCU, LVP, SYR, PCA, $EtCO_2$
Communication - RJ-45 and RS-232 Capability	PCU
Memory and Clock	
Memory Retention	PCU
Real-Time Clock Drift	PCU
Biocompatibility—Cytotoxicity, Irritation, and Sensitization	ALL
Electrical Safety and EMC	
Immunity to Electrostatic Discharge	ALL
Immunity to Radiated RF, Magnetic Fields, and Proximity RF Wireless Communication Equipment	ALL
Electrical Safety	ALL
Software Verification and Validation—Code Inspection, Static Analysis, Unit Testing, Black and Gray Box	Software
User Needs	
Validation by Simulated Testing	PCU, LVP, SYR, PCA
Validation by Clinical Assessment	PCU, LVP, SYR, PCA
Validation of Biomedical Engineering Use	PCU, LVP, SYR, PCA
Interoperability	PCU, LVP, Auto-ID
Human Factors/Useability Engineering	PCU, LVP, SYR, PCA, $EtCO_2$, Auto-ID and LVP for Anesthesia
Miscellaneous	
Available Sets Engineering Analysis	LVP, SYR, PCA
Flame Retardant Engineering Analysis	PCU, LVP, SYR, PCA, $EtCO_2$, Auto-ID
Latex Requirement Engineering Analysis	PCU, LVP, SYR, PCA, $EtCO_2$
PCA Monitoring Protocol Feature	PCU, PCA, $EtCO_2$

Animal Data

No animal data was generated in support of this Premarket Notification.

Clinical Data

No clinical data was generated in support of this Premarket Notification.

Conclusions

The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. The BD Alaris System with Guardrails Suite MX v12 is substantially equivalent to the Alaris System with Guardrails Suite MX cleared under K133532 with respect to the indications for use, target populations, treatment method, and technological characteristics.