



Food and Drug Administration
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August 21, 2014

CareFusion 303, Inc.
Christine Caton
Advisor, Regulatory Management
10020 Pacific Mesa Blvd.
SAN DIEGO, CA 92121

Re: K133532

Trade/Device Name: Alaris System with Guardrails Suite MX
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN, PHC
Dated: July 22, 2014
Received: July 23, 2014

Dear Ms. Caton

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Mary S. Runner -S

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control, and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K133532

Device Name

Alaris System with Guardrails Suite MX

Indications for Use (Describe)

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.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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“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.”

Section 4.6: 510(k) Summary

Alaris System with Guardrails Suite MX

510(k) Number K133532

510(k) Owner's Name:

CareFusion 303, Inc.
 10020 Pacific Mesa Blvd.
 San Diego, CA 92121 USA
 Establishment Registration Number: 2016493
 Owner/Operator Number: 9068764

Contact Person:

Christine Caton
 Advisor, Regulatory Management
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Date Summary was Prepared: 14 July 2014

Device Trade / Proprietary Name:

Alaris System with Guardrails Suite MX

Device Common / Classification Name:

Pump, Infusion

Device Class	Classification Panel	Regulation Number	FDA Product Code
2	General Hospital	21 CFR 880.5725	80F--RN
2	General Hospital	21 CFR 880.5725	80P--HC

Identification of the Legally Marketed Device to which the Submitter Claims Equivalence:

The proposed component device v10.5 software is similar to other devices of comparable type in commercial distribution as described in the most recently cleared 510(k)s, as listed below, and have the same intended use. Any differences in the technological characteristics do not raise different questions of safety and effectiveness.

Component Name	Model Number	FDA Product Code, Regulation	510(k) Number	
Alaris System Components				
Point-of-Care (PC) Unit Module	8015	80F--RN	K051641*	K091308
Large Volume Pump (LVP) Module	8100	21 CFR 880.5725	K950419*	K012383
Syringe Pump (SYR) Module	8110		K023264	N/A
Guardrails Suite MX Components				
Alaris Guardrails Editor (GRE) safety software	8961	80F--RN 21 CFR 880.5725	K072105*	K030459

*Primary

Description of the Device that is the Subject of the Premarket Notification Submission:

- **Indications for Use**

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.

- Intended Use

The Alaris System with Guardrails Suite MX is a modular infusion pump and vital signs monitoring system intended for adult, pediatric and neonatal care that includes safety management software to help reduce medication errors. The Alaris System consists of the PC Unit and up to four detachable infusion and/or monitoring modules (channels). The Auto-ID Module can be included as a fifth module.

The Alaris System with Guardrails Suite MX is intended for use by Healthcare Professionals in facilities that utilize infusion pumps for the delivery of fluids, medications, blood and blood products using continuous or intermittent delivery through clinically acceptable routes of administration such as intravenous (IV), intra-arterial (IA), subcutaneous, epidural, enteral or irrigation of fluid spaces.

- Contraindications

There are no known contraindications for the Alaris System with Guardrails Suite MX.

This is the **same Indications for Use and Intended Use** as previously cleared for the respective 510(k)s provided below. There have been no modifications. The verbiage has only been made consistent across the system.

- **Description of the Device as Found in the Labeling or Promotional Material / Intended Use**

The Alaris System with Guardrails Suite MX is similar to other devices of comparable type in commercial distribution. The indications for use/intended use, principles of operation, fundamental scientific technology, method of manufacture, and application have not changed. The following description is the same for the existing cleared device as for the proposed modified device.

The Alaris System with Guardrails Suite MX is a modular infusion pump and vital signs monitoring system intended for adult, pediatric and neonatal care that includes safety management software to help reduce medication errors.

The Alaris System with Guardrails Suite MX is intended to provide trained Healthcare Professionals with a way to automate the programming of infusion parameters, thereby decreasing the number of manual steps necessary to enter infusion parameters and provide a "safety net" at the patient's bedside. This helps to reduce the number of programming errors at the point-of-care. 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 can be integrated into an existing hospital network and allows communications to and from external devices including personal computers (PCs), Personal Digital

Assistants (PDAs), hospital monitoring systems and Hospital Information Management Systems (HIMS). Bi-directional communication of data can include infusion parameters, system configuration, clinical history, events, trending, alarms and status.

- Explanation of How the Device Functions

PC Unit remains the core of the Alaris System, providing a common user interface and power supply for associated system modules. The basic components of the PC Unit include:

- A mechanical interface which provides structural interconnection between the PC Unit and the modules.
- A power interface which provides power from the PC Unit to the modules.
- A communications interface which provides the ability to communicate bi-directionally between the PC Unit and the modules.
- A communications interface which provides the ability to communicate bi-directionally between the PC Unit and an external host.

- The Scientific Concepts that Form the Basis for the Device

Smart infusion pump systems can help prevent medication errors by alerting the healthcare professional to a pump setting that doesn't match the Healthcare Facility's drug administration guidelines programmed into the Data Set. By checking the programmed settings against the Healthcare Facility's Data Set for specific drugs and care areas, smart infusion pump systems can help the Healthcare Professional intercept and correct potentially serious infusion mistakes before they happen.

- Significant Physical and Performance Characteristics of the Device such as Design, Material and Physical Properties

The significant physical and performance characteristics of the infusion pump system are provided in the User Manuals.

- Summary of Technological Characteristics of the Proposed Device Compared to the Predicate Device

The proposed infusion pump system with the v10.5 software enhancements has the same technological characteristics as the predicate devices.

The affected component devices with the proposed v10.5 software enhancements have the following similarities as the predicate devices:

- Have the same indications for use and intended use.
- Apply the same operational principles.
- Have the same design.
- Have the same materials.
- Have the same components.
- Have similar operational flow.
- Have the same performance specifications.
- Have the same physical properties.
- Have the same manufacturing process.
- Have the same energy source.
- Have the same technological characteristics or have different technological characteristics (e.g., Detect Closed Secondary Clamp feature) and do not raise different questions of safety and effectiveness. There are no significant changes in the materials, design, energy source, or other features of the device from those of the predicates. The device is as safe and effective as the legally marketed device. This claim is supported by the information and data provided in this 510(k). This includes the following information:
 - Descriptions of the existing and proposed device systems.
 - Indications for Use and Intended Use of the existing and proposed device systems.

- Labeling for the existing and proposed device systems.
 - Comparison tables of features of the existing and proposed device systems.
 - Comparison tables of specifications of the existing and proposed device systems.
 - Proposed device system and software hazard analysis.
 - Proposed device system and software requirements.
 - Proposed device system and software test plans and reports.
 - Proposed device system and software traceability matrix.
- Discussion of Non-Clinical Tests Submitted, Referenced or Relied On in the 510(k) and the Conclusions Drawn

Software verification and validation was performed to ensure that the proposed v10.5 software enhancements meet design input and safety requirements. Software testing included verification and validation of the closed secondary clamp detection functions, input and output functions and user interface modifications. The proposed v10.5 software enhancements do not affect the indications for use/intended use or introduce any unacceptable risks. Verification and validation testing to support the v10.5 software enhancements has been completed and demonstrate that design verification testing including software verification and validation is acceptable and design outputs conform to the design input requirements. This confirms that the Alaris System with Guardrails Suite MX with the v10.5 software enhancements meet these requirements.

The proposed v10.5 software modifications did not require animal studies.

- Discussion of Clinical Tests Submitted, Referenced or Relied On in the 510(k) and the Conclusions Drawn

This 510(k) does not include clinical data.