K043590

SUMMARY OF SAFETY AND EFFECTIVENESS
Cardinal Health, Alaris Products
SE Infusion System with MMS

SUBMITTER INFORMATION

A.	Company Name:	Cardinal Health, Alaris Products
B.	Company Address:	10221 Wateridge Circle San Diego, CA 92121-2733
C.	Company Phone: Company Fax:	(858) 458-7830 (858) 458-6114
D.	Contact Person:	Stacy L. Lewis Sr. Regulatory Affairs Specialist
E.	Date Summary Prepared:	December 23, 2004

DEVICE IDENTIFICATION

A.	Generic Device Name:	Pump, Infusion
B.	Trade/Proprietary Name:	SE Infusion System with MMS
C.	Classification:	Class II
D.	Product Code:	FRN, Infusion Pump

DEVICE DESCRIPTION

The addition of the Medication Management System (MMS) to the SE Infusion System will allow wireless bi-directional communication with the Alaris Server and external devices. MMS is the combination of RF communication from the SE Infusion System to/from the Alaris Server and the Alaris Proprietary software called the Inter-Server Interface Protocol (ISIP). The ISIP allows for communication between the SE Infusion System, the Alaris Server, and external devices.

The SE Infusion System with MMS is intended to provide a way to automate the programming of infusion parameters, thereby decreasing the amount of manual steps

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DEVICE DESCRIPTION (Continued)

necessary to enter infusion data. All data entry and verification of infusion or monitoring parameters using MMS is performed by trained healthcare professionals prior to administration of medication(s).

SUBSTANTIAL EQUIVALENCE

The Cardinal Health, Alaris Products SE Infusion System with MMS is of comparable type and is substantially equivalent to the following predicate device:

Predicate Device	Manufacturer	510(k) No.	Date Cleared
Medley System with MMS	Cardinal Health, Alaris Products (previously known as Alaris Medical Systems, Inc.)	K030459	April 4, 2003

INTENDED USE

The incorporation of the Medication Management System (MMS) with the Alaris SE Infusion System provides wired or wireless communication between the SE Infusion System and external devices. This is intended to provide a way to automate the programming of infusion parameters, thereby decreasing the amount of manual steps to enter infusion data. All data entry and validation of infusion parameters using MMS is performed by the trained healthcare professional. A separate Indications for Use page is located in **Section 6**.

TECHNOLOGICAL CHARACTERISTICS

A comparison of the technological characteristics of the SE Infusion System with MMS and the predicate device has been performed. The results of this comparison demonstrate that the SE Infusion System with MMS is equivalent to the marketed predicate device in technological characteristics.

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PERFORMANCE DATA

The performance data indicate that the SE Infusion System with MMS meets specified requirements, and is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 25 2005

Ms. Stacy L. Lewis
Senior Regulatory Affairs Specialist
Cardinal Health, Alaris Products
10221 Wateridge Circle
San Diego, California 92121-2772

Re: K043590
Trade/Device Name: SE Infusion System with MMS
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: December 23, 2004
Received: December 28, 2004

Dear Ms. Lewis:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K043590 (To Be Assigned By FDA)

Device Trade Name: **SE Infusion System with MMS**

Indications For Use: The SE Infusion System with MMS is intended for use in today's growing professional healthcare environment for facilities that utilize infusion devices for the delivery of fluids, medications, blood and blood products.

The SE Infusion System with MMS 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.

Prescription Use ___X___ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

(510(k) Number K043590