K051641

SUMMARY OF SAFETY AND EFFECTIVENESS
Cardinal Health, Alaris Products®
Alaris System with Enhanced PC Unit

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 Cardinal Health, Alaris Products
E.	Date Summary Prepared:	June 15, 2004

DEVICE IDENTIFICATION

A.	Generic Device Name:	Infusion Pump
B.	Trade/Proprietary Name:	Alaris System PC Unit
C.	Classification:	Class II
D.	Product Code:	FRN, Infusion Pump

DEVICE DESCRIPTION

The Alaris System is a modular system that consists of a point-of-care unit (PC Unit) that provides the main user interface and power supply for the associated infusion and monitoring modules. The Enhanced PC Unit will include a faster processor, increased memory, and a color screen. This update is only for the Alaris PC Unit and does not require any change to the associated modules, systems, or accessories of the Alaris System.

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SUBSTANTIAL EQUIVALENCE

The Cardinal Health, Alaris Products Alaris System with Enhanced PC Unit is substantially equivalent to the following predicate device:

Predicate Device	Manufacturer	510(k) No.	Date Cleared
Alaris System (originally submitted as IMED Orion Infusion System)	Cardinal Health, Alaris Products	K950419	June 21, 1995

INTENDED USE

The Alaris PC Unit is the main user interface unit and power supply of the Alaris System, a modular system to be used with Alaris System modules (aka Medley System modules) intended for use in today's growing professional healthcare environment for facilities that utilize infusion and/or monitoring devices. The specific intended use for each Alaris System module is specified in it's respective submission.

TECHNOLOGICAL CHARACTERISTICS

A comparison of the technological characteristics of the Alaris System with Enhanced PC Unit and the predicate device has been performed. The results of this comparison demonstrate that the Alaris System with Enhanced PC Unit is equivalent to the marketed predicate device in technological characteristics.

PERFORMANCE INFORMATION

The performance information provided indicates that the Alaris System with Enhanced PC Unit 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

OCT 2 0 2005

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

Re: K051641
Trade/Device Name: ALARIS SYSTEM PC UNIT, MODEL 8001
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: September 22, 2005
Received: September 23, 2005

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: K051641 (To Be Assigned By FDA)

Device Trade Name: **Alaris System PC Unit**

Indications For Use: The Alaris PC Unit is the main user interface unit and power supply of the Alaris System, a modular system to be used with Alaris System modules (aka Medley System modules) intended for use in today's growing professional healthcare environment for facilities that utilize infusion and/or monitoring devices. The specific intended use for each Alaris System module is specified in its respective submission.

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: K051641