ATTACHMENT D

K072105

SUMMARY OF SAFETY AND EFFECTIVENESS
Cardinal Health 303, Inc.
Alaris® System with MMS

DEC 2 8 2007

SUBMITTER'S NAME: **Cardinal Health 303, Inc.**
d.b.a. Cardinal Health
10221 Wateridge Circle
San Diego, CA 92121-2772
(858) 458-7830
(858) 458-6114 FAX

CONTACT PERSON: **Stacy L. Lewis**
Principal Regulatory Affairs Specialist

DATE PREPARED: **July 27, 2007**

DEVICE NAME: **Proprietary Name**
Alaris® System with MMS

Common Name
Infusion Pump

Classification Name
Pump, Infusion and accessories, FRN (880.5725)

PREDICATE DEVICE: Alaris® System with MMS (a.k.a. Medley™ System with MMS), K030459

DEVICE DESCRIPTION

As with the predicate device, the Alaris® System with MMS assists our customers in reducing the number of manual steps needed to program an infusion by allowing wireless communication capability to a server and an existing infusion device (the Alaris® System). The wireless communication capability provides a "safety net" at the bedside to help reduce the number of programming errors at the point of care. It allows the Alaris® System to transmit and receive messages with the Alaris® Server which in turn allows communication capability with external devices, including personal computers, Personal Digital Assistants (PDA;s), hospital monitoring systems and Hospital Information Management Systems (HIMS).

ALARIS® SYSTEM WITH MMS
SUMMARY OF SAFETY AND EFFECTIVENESS
Page 2 of 2

SUBSTANTIAL EQUIVALENCE

The Alaris® System with MMS is essentially the same as the predicate device in that they have the same intended use, operating principles, method of operation, technology, materials and manufacturing processes. The changes as described in this Special 510(k) pose no new issues of safety or efficacy. The Alaris® System with MMS as described in this submission is substantially equivalent to the predicate device.

INTENDED USE

The incorporation of the Medication Management System (MMS) with the Alaris® System (a.k.a. Medley™ System) provides wired or wireless communication between the Alaris® 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.

The Alaris® System with MMS is integrated into an existing hospital network infrastructure and allows communications to and from external devices, including personal computers, Personal Digital Assistants (PDAs), hospital monitoring systems and Hospital Information Management Systems (HIMS). Bi-directional communication of data includes infusion parameters, system configuration, history, events, trending, alarms and status. In addition the Alaris® System with MMS has the capability to transmit, receive and/or store: features, calibration data, datasets, and libraries from external components or devices to the pump.

TECHNOLOGICAL CHARACTERISTICS

A comparison of the technological characteristics of the Alaris® System with MMS and the predicate device has been performed. The results of this comparison demonstrate that the Alaris® System with MMS is equivalent in technological characteristics and the fundamental scientific technology of the predicate device has not been altered.

00768

K072105 pg 2 of 2

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 8 2007

Ms. Stacey L. Lewis
Principal Regulatory Affairs Specialist
Cardinal Health 303, Incorporated
10221 Wateridge Circle
San Diego, California 92121

Re: K072105
Trade/Device Name: Alaris® System with MMS
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: December 3, 2006
Received: December 4, 2006

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Sheila A Murphy MD for Chiu Lin, Ph.D

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

Attachment B

INDICATIONS FOR USE

510(k) Number: K072105 (To Be Assigned By FDA)

Device Trade Name: **Alaris® System with MMS**

Indications For Use:

The Alaris® System with Medication Management System (also known as the Medley™ System with MMS and the Alaris® 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 Alaris® 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 _____

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

_____ _____ _____ _____ _____

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

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

510(k) Number: K072105

00763