SUMMARY OF SAFETY AND EFFECTIVENESS
ALARIS Medical Systems, Inc.
Medley System with MMS

K030459

SUBMITTER INFORMATION

A.	Company Name:	ALARIS Medical Systems, Inc.
B.	Company Address:	10221 Wateridge Circle San Diego, CA 92121-2733
C.	Company Phone: Company Fax:	(858) 458-7563 (858) 458-6114
D.	Contact Person:	Renée L. Fluet Principal Regulatory Affairs Specialist ALARIS Medical Systems, Inc.
E.	Date Summary Prepared:	February 3, 2003

DEVICE IDENTIFICATION

A.	Generic Device Name:	Pump, Infusion
B.	Trade/Proprietary Name:	Medley™ System with Medication Management System (Medley™ System with MMS)
C.	Classification:	Class II
D.	Product Code:	FRN, Infusion Pump

DEVICE DESCRIPTION

The Medley™ System (K950419) is a currently marketed modular infusion and monitoring system that consists of a Programming Module (PM) and attachable/detachable modules. Current infusion modules available are a Pump Module (K950419) and a Syringe Module (K023264). Monitoring modules currently include Pulse Oximetry (SpO_2) using Nellcor (K022677) and Masimo (K010966) technology.

SUMMARY OF SAFETY AND EFFECTIVENESS

DEVICE DESCRIPTION, Continued

This traditional 510(k) Premarket Notification is being submitted to assist our customers in reducing the number of manual steps needed to program an infusion by allowing wireless communication capability to the currently marketed device, the Medley™ Medication Safety System (Medley System) K950419. This Medication Management System (MMS) adds communication capability to the Medley™ System thereby providing our customers with a "safety net" at the bedside to help reduce the number of programming errors at the point of care. This product will be called the Medley System with MMS.

As with the predicate device (B. Braun Medical Inc., Horizon™ Outlook with DoseCom™) this submission adds wireless communication to a server and to an existing infusion device. The Medley System was originally cleared with the capability of wired or wireless communication to include receiving infusion protocol information, uploading/downloading system configuration information and reporting infusion or system status. However, this capability was not well defined and did not include communication with a Server. It was also not clear about the local retrieval of data using optical laser scanning (bar-coding) or RF detection of information contained in documents, labels, RF ID Chips, etc. Adding MMS to the Medley System is simply an expansion of the original 510(k) indications for use for the Medley System. This submission will allow the Medley 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).

SUMMARY OF SAFETY AND EFFECTIVENESS, Continued

SUBSTANTIAL EQUIVALENCE

The ALARIS Medical Systems Inc., Medley™ System with MMS is substantially equivalent to the following predicate device:

Predicate Device	Manufacturer	510(k) No.	Date Cleared
Horizon Outlook™ with Dose Com™	B. Braun Medical, Inc.	K011975	09/19/01

In further support of a substantial equivalence determination, **Section 9.2** provides a comparison chart of the Medley™ System with MMS and the predicate device.

INTENDED USE

The incorporation of the Medication Management System (MMS) with the ALARIS Medley Medication Safety System provides wired or wireless communication between the Medley 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 Medley System with MMS is integrated into an existing hospital network infrastructure and allows communications to and from external devices, including personal computers (PC's), 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 Medley 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.

SUMMARY OF SAFETY AND EFFECTIVENESS, Continued

TECHNOLOGICIAL CHARACTERISTICS

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

PERFORMANCE DATA

The performance data indicate that the Medley™ 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

APR 0 4 2003

Ms. Renée L. Fluet
Principal Regulatory Affairs Specialist
ALARIS, Medical Systems, Incorporated
10221 Wateridge Circle
San Diego, California 92121-2733

Re: K030459
Trade/Device Name: Medley™ System with Medication Management System (Medley™ System with MMS)
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: February 3, 2003
Received: February 11, 2003

Dear Ms. Fluet:

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.

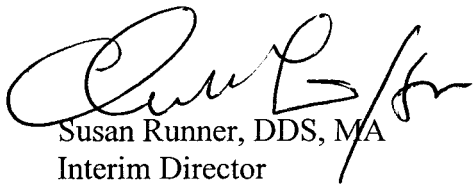
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4618. 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/dsma/dsmamain.html

Sincerely yours,



Susan Runner, DDS, MA
Interim 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: K030459 (To Be Assigned By FDA)

Device Trade Name: **Medley™ System with Medication Management System (Medley™ System with MMS)**

Indications For Use: The ALARIS Medical Systems, Inc., Medley™ System with Medication Management System (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 Medley™ 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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109) Melissa C. Lucente

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

510(k) Number: K030459