K041241

SUMMARY OF SAFETY AND EFFECTIVENESS
ALARIS Medical Systems®
Medley™ System with Bar Code Module

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) 458-7830 (858) 458-6114
D.	Contact Person:	Stacy L. Lewis Sr. Regulatory Affairs Specialist ALARIS Medical Systems, Inc.
E.	Date Summary Prepared:	May 10, 2004

DEVICE IDENTIFICATION

A.	Generic Device Name:	Infusion Pump
B.	Trade/Proprietary Name:	Medley™ System with Bar Code Module
C.	Classification:	Class II
D.	Product Code:	FRN, Infusion Pump

DEVICE DESCRIPTION

The Medley Bar Code Module functions as part of the Medley System and can operate as a fifth module (when all four infusion and/or monitoring positions are in use). The Medley Bar Code Module attaches to and receives its power from the Medley System consistent with the modular design. The Bar Code Module does not directly interface with the Medley System; all communications are routed using a separate and dedicated communications interface channel resident in the Medley System.

SUMMARY OF SAFETY AND EFFECTIVENESS
ALARIS Medical Systems®
Medley™ System with Bar Code Module
Page 2 of 3

Through the dedicated communications channel, the Medley Bar Code Module exchanges information between itself and other sources, such as the patient wristband, medication or device packaging, Medley, or MMS System components such as the ALARIS Server and Hospital Information Management Systems. As with the Medley System with MMS, there is an information protocol for proprietary data exchange and a method to verify the integrity of the information sent or received prior to programming a Medley System infusion module. The software incorporates error checking to ensure the correct acquisition, exchange, and integrity of acquired bar coded data.

All data entry and verification of infusion parameters using the Medley System with Bar Code Module is performed by trained healthcare professionals prior to administration of medication(s). The Medley Bar Code Module does not affect the operation of the Medley System. All Medley System functionality and performance specifications remain unchanged.

An attachable/detachable handheld scanner will be provided as an accessory to the Medley System with Bar Code Module as alternative way to acquire bar code data.

SUBSTANTIAL EQUIVALENCE

The ALARIS Medical Systems® Medley™ Bar Code Module is of comparable type and is substantially equivalent to the following predicate devices:

Predicate Device	Manufacturer	510(k) No.	Date Cleared
Medley System w/ MMS	ALARIS Medical Systems, Inc.	K030459	April 4, 2003
Horizon Outlook 200	B. Braun	K011975	Sept. 19, 2001

SUMMARY OF SAFETY AND EFFECTIVENESS
ALARIS Medical Systems®
Medley™ System with Bar Code Module
Page 3 of 3

INTENDED USE

The Medley System with Bar Code Module 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 Bar Code Module 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.

TECHNOLOGICAL CHARACTERISTICS

A comparison of the technological characteristics of the Medley™ Bar Code Module and the predicate devices has been performed. The results of this comparison demonstrate that the Medley™ Bar Code Module is equivalent to the marketed predicate devices in technological characteristics.

PERFORMANCE DATA

The performance data indicate that the Medley™ Bar Code Module meets specified requirements, and is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 6 2004

Ms. Stacy L. Lewis
Senior Regulatory Affairs Specialist
ALARIS Medical Systems, Incorporated
10221 Wateridge Circle
San Diego, California 92121-2772

Re: K041241
Trade/Device Name: Medley™ System with Bar Code Module
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: May 10, 2004
Received: May 11, 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.

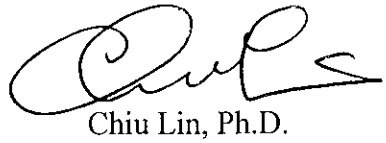
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

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 (if known): K041241

Device Name: Medley™ System with Bar Code Module

Indications For Use:

The Medley System with Bar Code Module 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 Bar Code Module 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 AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(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: K041241