K032233

SUMMARY OF SAFETY AND EFFECTIVENESS
ALARIS Medical Systems®
Medley™ PCA 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 Regulatory Affairs Associate ALARIS Medical Systems, Inc.
E.	Date Summary Prepared:	July 17, 2003

DEVICE IDENTIFICATION

A.	Generic Device Name:	PCA Infusion Pump
B.	Trade/Proprietary Name:	Medley™ PCA Module
C.	Classification:	Class II
D.	Product Code:	MEA, PCA Infusion Pump

DEVICE DESCRIPTION

The Medley PCA Module functions as part of the Medley™ Medication Safety System. In combination with the Medley™ Programming Module (PM), the PCA Module will deliver fluids in a manner similar to current PCA pumps on the market. The Medley™ PCA Module uses standard non-dedicated, single-use, administration sets and syringes with luer-lock connectors, of type designed for use on syringe-type PCA pumps.

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SUBSTANTIAL EQUIVALENCE

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

Predicate Device	Manufacturer	510(k) No.	Date Cleared
Medley Syringe Module	ALARIS Medical Systems, Inc.	K023264	12/19/02
Baxter PCA II Pump	Baxter Healthcare Corporation	K921994	8/3/92

INTENDED USE

The Medley PCA Module is intended for use in today's growing professional healthcare environment for facilities that utilize syringe pumps for the delivery of medications or fluids.

The Medley PCA Module is indicated for use on adults, pediatrics, and neonates for continuous or intermittent delivery through clinically acceptable routes of administration; such as, intravenous (IV), subcutaneous, or epidural.

TECHNOLOGICAL CHARACTERISTICS

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

PERFORMANCE DATA

The performance data indicate that the Medley™ PCA 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

SEP - 9 2003

Ms. Stacy L. Lewis
Regulatory Affairs Associate
Alaris Medical System, Incorporated
10221 Wateridge Circle
San Diego, California 92121-2772

Re: K032233
Trade/Device Name: PCA Infusion Pump
Regulation Number: 880.5275
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: MEA, FRN
Dated: July 17, 2003
Received: July 21, 2003

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 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: K032233 (To Be Assigned By FDA)

Device Trade Name: **Medley™ PCA Module**

Indications For Use: The Medley PCA Module is intended for use in today's growing professional healthcare environment for facilities that utilize syringe pumps for the delivery of medications or fluids.

The Medley PCA Module is indicated for use on adults, pediatrics, and neonates for continuous or intermittent delivery through clinically acceptable routes of administration; such as, intravenous (IV), subcutaneous, or epidural.

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)

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

510(k) Number: K032233