K031741

SUMMARY OF SAFETY AND EFFECTIVENESS
ALARIS Medical Systems®
Medley™ $EtCO_2$ 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) 458-7563 (858) 458-6114
D.	Contact Person:	Renée L. Fluet Principal Regulatory Affairs Specialist ALARIS Medical Systems, Inc.
E.	Date Summary Prepared:	June 3, 2003

DEVICE IDENTIFICATION

A.	Generic Device Name:	Capnograph / $EtCO_2$ Monitor
B.	Trade/Proprietary Name:	Medley™ System with $EtCO_2$ Module
C.	Classification:	Class II
D.	Product Code:	CCK, Capnograph

DEVICE DESCRIPTION

The $EtCO_2$ Module is the newest module to be added to the currently marketed Medley™ Medication Safety System (Medley™ System). ALARIS Medical will incorporate currently marketed Oridion capnograph technology and accessories into the Medley™ $EtCO_2$ Module. The Medley™ $EtCO_2$ Module will be used to measure inspired and expired carbon dioxide ($FiCO_2$ and $EtCO_2$ respectively) and Respiration Rate (RR) on patients in the operating room, ICU, NICU, transport and emergency treatment. This capnograph technology originates from the MediCap/NPB-75 (K964239). The current

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line of Oridion Microstream accessories for use with the Medley™ $EtCO_2$ Module are listed below:

- K011536 Microstream O_2/CO_2 Oral Nasal Filterline
- K011050 Microstream Oral Nasal, Cannula Filterline
- K980324 Microstream Filterline OR/EMS
- K980325 Microstream Nasal Cannula Filterline
- K980327 Microstream Filterline ICU

SUBSTANTIAL EQUIVALENCE

The ALARIS Medical Systems® Medley™ System with $EtCO_2$ Module is of comparable type and is substantially equivalent to the following predicate device:

Predicate Device	Manufacturer	510(k) No.	Date Cleared
MicroCap/NPB-75	Oridion Medical Ltd. (formally known as Spegas Industries, Inc.)	K964239	05/09/97

INTENDED USE

The Medley™ $EtCO_2$ Module is a capnograph that continuously monitors end tidal carbon dioxide ($EtCO_2$), fractional inspired carbon dioxide ($FiCO_2$), and respiratory rate (RR). The monitor is intended for use by professional healthcare providers where continuous, non-invasive monitoring of these parameters is desired.

The Medley™ $EtCO_2$ Module is indicated for use on adults, pediatrics and infant/neonates for both intubated and non-intubated patients.

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TECHNOLOGICAL CHARACTERISTICS

A comparison of the technological characteristics of the Medley™ System with $EtCO_2$ Module and the predicate device has been performed. The results of this comparison demonstrate that the Medley™ System with $EtCO_2$ Module is equivalent to the marketed predicate device in technological characteristics.

PERFORMANCE DATA

The performance data included in this submission indicate that the Medley™ $EtCO_2$ 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

FEB - 9 2004

Ms. Renee L. Fluet
Principal Regulatory Affairs Specialist
Alaris Medical Systems, Incorporated
Corporate Office
10221 Wateridge Circle
San Diego, California 92121-2733

Re: K031741
Trade/Device Name: Medley EtCO2 Module
Regulation Number: 868.1400
Regulation Name: Analyzer, Gas, Carbon-Dioxide, Gaseous-Phase
Regulatory Class: II
Product Code: CCK
Dated: January 9, 2004
Received: January 12, 2004

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) 594-4646. 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,

for 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: K031741 (To Be Assigned By FDA)

Device Trade Name: **Medley™ System with $EtCO_2$ Module**

Indications for Use: The Medley $EtCO_2$ Module is a capnograph that continuously monitors end tidal carbon dioxide ($EtCO_2$), fractional inspired carbon dioxide ($FiCO_2$), and respiratory rate (RR). The monitor is intended for use by professional healthcare providers where continuous, non-invasive monitoring of these parameters is desired.

The Medley ™ $EtCO_2$ Module is indicated for use on adults, pediatrics and infant/neonates for both intubated and non-intubated patients.

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: K031741