K012383

SUMMARY OF SAFETY AND EFFECTIVENESS
ALARIS Medical Systems®, Inc.

SUBMITTER INFORMATION

A.	Company Name:	**ALARIS Medical Systems, Inc.**
B.	Company Address:	10221 Wateridge Circle San Diego, CA 92121
C.	Company Phone: Company Fax:	(858) 458-7563 (858) 458-6223
D.	Contact Person:	Renée L. Fluet Principal Regulatory Affairs Specialist
E.	Date Summary Prepared:	July 26, 2001

DEVICE IDENTIFICATION

A.	Generic Device Name:	Infusion Pump
B.	Trade/Proprietary Name:	Pump, Infusion
C.	Classification	Pump, Infusion, 21CFR 880.5725, Class II Product Code FRN

SUBSTANTIAL EQUIVALENCE

The ALARIS Medical Systems line of infusion pumps as listed below are of comparable type and are substantially equivalent to the predicate devices, the Abbott Plum XL and Baxter's line of Colleague® Infusion Pumps.

ALARIS Medical Infusion Pumps	510(k) #	Date Cleared
IMED Gemini PC-1 Volumetric Infusion Pump	K883993	12/19/88
IMED Gemini PC-4 Volumetric Infusion Pump	K921370	06/09/92
IVAC Signature Edition Volumetric Infusion Pumps	K931549	10/12/93
IMED Gemini PC-2TX Volumetric Infusion Pump	K933144	10/12/93
IVAC MedSystem III Volumetric Infusion Pumps	K933545	09/29/94
ALARIS Medical Medley Patient Care System	K950419	6/21/95
IVAC MedSystem III Volumetric Infusion Pump with DLE	K961486	04/17/98

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Predicate Device(s)

Manufacturer and Device	510(k) #	Date Cleared
Abbott Plum XL Infusion Pump	K010924	04/06/01
Colleague Volumetric and CX Volumetric Infusion Pumps	K002211	08/28/00

DEVICE DESCRIPTION

ALARIS Medical Systems line of infusion pumps are electrical volumetric infusion pumps that are used to control the rate or monitor the flow of solution or medication. In general, infusion pumps are used when the solution to be administered needs to be delivered with greater accuracy or at a higher flow than can be provided through a manually adjusted gravity administration set. Because they allow more accurate fluid delivery, infusion pumps have proven to be useful in applications such as continuous epidural anesthesia, enteral delivery, administration of IV cardiovascular drugs, chemotherapy, and blood transfusions.

This 510(k) Premarket Notification is being submitted to expand the intended use to include specific indications for ALARIS Medical infusion pumps. The current indications will expand to include detailed information such as administration route, target population, and intended user. This expansion will serve to better represent the ALARIS Medical infusion pump as used in today's healthcare environment, as well as, provide a better competitive comparison with other infusion pumps. Expansion of the indications as described in this submission does not alter the intended use of the device nor does it affect performance, safety, or efficacy of any of the devices.

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INTENDED USE

ALARIS Medical Systems infusion pumps are intended for use in today's growing professional healthcare environment including hospitals, healthcare facilities, home care and medical transport that utilize infusion pumps for the delivery of fluids, medications, blood and blood products.

The following ALARIS Medical Systems infusion pumps are indicated for continuous or intermittent delivery through clinically acceptable routes of administration such as intravenous (IV), intra-arterial (IA), subcutaneous, epidural, enteral, or irrigation of fluid spaces:

- IMED® Gemini Infusion Pump / Controllers model PC-1®
- IMED Gemini Infusion Pump / Controllers model PC-2®
- IMED Gemini Infusion Pump/Controller model PC-2TX®
- IMED Gemini Infusion Pump/Controller model PC-4®
- IVAC® Signature Edition® Infusion Pumps
- IVAC MedSystem III® Multi-channel Infusion Pumps
- IVAC MedSystem III® Multi-channel Infusion Pumps with DLE
- ALARIS Medical Medley™ Patient Care System

Note: See the appropriate Directions for Use (DFU) for infusion system specifications.

TECHNOLOGICAL CHARACTERISTICS

A comparison of the technological characteristics of the ALARIS Medical line of infusion pumps and the predicate devices has been performed. The results of this comparison demonstrate that the ALARIS Medical Line of infusion pumps with expanded indications for use are equivalent to the original 510(k) devices as well as, the Abbott Plum XL Infusion Pump (K010924) and the Baxter Healthcare line of Colleague® Infusion Pumps (K002211).

PERFORMANCE DATA

There are no changes to the devices to support the expansion of indications. Therefore performance data is not necessary.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 2 2001

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

Re: K012383
Trade/Device Name: ALARIS Medical Systems® Infusion Pump
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: July 26, 2001
Received: July 27, 2001

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K012383 **(To Be Assigned By FDA)**

Device Trade Name: **ALARIS Medical Systems® Infusion Pumps**

Indications for Use:

ALARIS Medical Systems infusion pumps are intended for use in today's growing professional healthcare environment including healthcare facilities, home care, and medical transport that utilize infusion pumps for the delivery of fluids, medications, blood and blood products.

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- IMED® Gemini Infusion Pump/Controller model PC-4®
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- IVAC® MedSystem III®, Multi-channel Infusion Pumps
- IVAC® MedSystem III® Multi-channel Infusion Pumps with DLE
- ALARIS Medical Medley™ Patient Care System

Note: See the appropriate Directions for Use (DFU) for infusion system specifications.

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 Dental, Infection Control,
and General Hospital Devices
510(k) Number K012383