ATTACHMENT D

SUMMARY OF SAFETY AND EFFECTIVENESS
ALARIS Medical Systems, Inc.
Signature Edition Infusion System

SUBMITTER'S NAME: **ALARIS Medical Systems, Inc.**
10221 Wateridge Circle
San Diego, CA 92121-2772
(858) 458-7830
(858) 458-6114 FAX

CONTACT PERSON: **Stacy L. Lewis**
Regulatory Affairs Associate

DATE PREPARED: July 10, 2003

DEVICE NAME: **Proprietary Name**
Signature Edition Infusion System

Common Name
Infusion Pump
IV Administration Sets

Classification Name
Pump, Infusion and accessories, FRN (880.5725)
Administration Sets, Intravascular, FPA (880-5440)

PREDICATE DEVICES: EZ 1 and EZ 2 Infusion Pumps, K931549
EZ Administration Sets, K931550

DEVICE DESCRIPTION

This device is essentially the same as the originally submitted devices (the predicate devices), filed as Models EZ 1 and EZ 2 Infusion Pumps (K931549) and EZ Administration Set Series (K931550). The electrical volumetric pumps and administration sets are used to control the rate or monitor the flow of solution or medication for delivery of drugs, fluids, and blood products. In general, infusion systems 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

SUMMARY OF SAFETY AND EFFECTIVENESS

delivery, infusion systems have been proven to be useful in applications such as continuous epidural anesthesia, administration of IV cardiovascular drugs, chemotherapy, and blood transfusions. See **Section 5** for a detailed device description and comparison.

SUBSTANTIAL EQUIVALENCE

The Signature Edition Infusion System is essentially the same as the predicate devices in that they have the same intended use, operating principles, technological design, incorporate similar materials and manufacturing processes. The changes as described in this Special 510(k) pose no new issues of safety or efficacy. The Signature Edition Infusion System as described in this submission is substantially equivalent to the predicate devices. See **Section 6** for substantial equivalence details and a comparison table.

INTENDED USE

The intended use of this device has not changed from the original submissions in terms of content or intent. The Signature Edition Infusion System (infusion pumps and administration sets) is intended for use in today's growing professional healthcare environment including healthcare facilities, home care, and medical transport that utilize infusion systems for the delivery of fluids, medications, blood and blood products. A separate **Indications for Use** statement is provided in **Attachment B.**

TECHNOLOGICAL CHARACTERISTICS

A comparison of the technological characteristics of the Signature Edition Infusion System and the predicate devices has been performed. The results of this comparison demonstrate that the Signature Edition Infusion System is equivalent in technological characteristics and the fundamental scientific technology of the predicate devices has not been altered.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 25 2003

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

Re: K032147
Trade/Device Name: Signature Edition Infusion Pump
Regulation Number: 880.5275, 880. 5440
Regulation Name: Infusion Pump and Administration Set
Regulatory Class: II
Product Code: FRN, FPA
Dated: July 10, 2003
Received: July 14, 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, and 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,

for Susan Runner, DDDS, MA
Interim Director
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment B

INDICATIONS FOR USE

510(k) Number: _____ (To Be Assigned By FDA)

Device Trade Name: **Signature Edition Infusion System**

Indications For Use:

The Signature Edition Infusion System (infusion pumps and administration sets) is intended for use in today's growing professional healthcare environment including healthcare facilities, home care, and medical transport that utilize infusion systems for the delivery of fluids, medications, blood and blood products.

The Signature Edition Infusion System is 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.

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

_____ _____ _____ _____ _____

Concurrence of CDRH, Office of Device Evaluation (ODE)

Marcia Cuanto

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

510(k) Number K032147

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)