AUG 1 2000

K993524

ALARIS™
MEDICAL SYSTEMS

Advantis™ ASC Infusion Pump System
510(k) Premarket Notification

SUMMARY OF SAFETY AND EFFECTIVENESS

1. **SUBMITTER'S NAME:**

ALARIS Medical Systems, Inc.
10221 Wateridge Circle
San Diego, CA 92121-2733
(619) 458-7563
(619) 458-6223 FAX

CONTACT PERSON:

Renée L. Fluet
Sr. Regulatory Affairs Specialist

DATE PREPARED: October 15, 1999

2. **DEVICE NAME:**

Proprietary Name:
Advantis ASC Infusion System

Common Name:
Infusion Pump and Administration Set

Classification Name:
Infusion Pump and Intravascular Administration Set

3. **PREDICATE DEVICES:**

Sabratek Corporation
Sabratek 3030 Infusion Pump
K914589

Baxter Healthcare Corporation
Flo-Gard 6201 Infusion Pump
K915522

Baxter (under Travenol Laboratories)
Continu-Flo Admin Set, Code 2C/200
K792538

4. **DEVICE DESCRIPTION:**

The Advantis™ ASC (Alternate Site Care) is a multi-mode large volume infusion pump suitable for general and homecare applications. The instrument is a microprocessor-controlled device designed to use a standard, single use, administration set (dedicated and non-dedicated).

0004

SUMMARY OF SAFETY AND EFFECTIVENESS (Continued)

4. DEVICE DESCRIPTION (Continued):

The large volume infusion pump provides control of infusion rates (0.1 ml/hr to 999 ml/hr) due to the positive displacement action of the linear peristaltic mechanism. The instrument's features include multi programs (standard, micro, primary, secondary modes), TPN and 10-P delivery, free flow protection, user selectable occlusion pressures, automatic priming, and an anti-bolus system.

This instrument incorporates both audible and visual alarms for Air-in-line, Upstream and Downstream Occlusion, Low Battery, Electrical or Mechanical Failure, Open Door and Incorrect IV Administration Set.

5. INTENDED USE:

The Advantis ASC is intended to be used for intravascular administration of drugs, fluids, blood and blood products and epidural applications.

6. TECHNOLOGICAL CHARACTERISTICS:

The Advantis ASC is similar to the Sabratek 3030 Volumetric Infusion Pump (Sabratek Corporation, K914589) and the Baxter Flo-Gard 6201 Infusion Pump (Baxter Healthcare Corporation, K915522). All devices have the same general design and incorporate similar technologies, software, materials, electronics, energy sources, and mechanical components.

The Advantis ASC administration sets are the same as the IV sets utilized by both the Sabratek and Baxter devices: Baxter administration sets (cleared under Travenol Laboratories) as "Continu-Flo Admin Sets, 2C/200", K792538. These sets are standard PVC sets with no proprietary pumping segment. In addition, Baxter added blood and epidural use with K900699, "Flo-Gard 6300 Blood Pumping Indication" (blood use) and K913895, "Flo-Gard 6200, 6300 & 8000" (epidural use). The sets have similar intended use, technological characteristics, materials, components, and labeling.

0005

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 2000

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

Re: K993524
Trade Name: Advantis ASC Infusion Pump and Administation Sets
Regulatory Class: II
Product Code: FRN
Dated: May 12, 2000
Received: May 15, 2000

Dear Ms. Fluet:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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

ALARIS™
MEDICAL SYSTEMS

Advantis™ ASC Infusion System
510(k) Premarket Notification

INDICATIONS FOR USE

510(k) Number (if known): K993524

Device Name: **Advantis ASC Infusion System**

Indications for Use: The Advantis ASC is intended to be used for intravascular administration of drugs, fluids, blood and blood products. This device is also indicated for epidural applications. The final DFU will contain all necessary precautions and recommendations for safe epidural application.

ALARIS Medical's policy is to not indicate specific drugs and/or fluids except in cases when a device is designed specifically or solely for a particular drug or fluid. Consistent with this policy, we would contraindicate drugs and/or fluids as appropriate for the Advantis ASC. No such contraindications have been identified.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X 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 K993524

0007