APR 17 1996

K961486

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

1. **SUBMITTER'S NAME:** IVAC Medical Systems, Inc.
10221 Wateridge Circle
San Diego, California 92121
(619) 458-7563

CONTACT PERSON: Renée L. Fluet
Regulatory Affairs Specialist

DATE PREPARED: April 12, 1996

2. **DEVICE NAME:**

Proprietary Name: IVAC MedSystem III™ Infusion Pump with Drug Editing Software Kit (DESK)

Common Name: Infusion Pump

Classification Name: Infusion Pump

3. **PREDICATE DEVICE:** IVAC MedSystem III™ Infusion Pump

4. **DEVICE DESCRIPTION:** The DESK is a PC-based software tool operated under Microsoft Windows. This software tool will be used to customize the drug list for the Dose Rate Calculator (DRC) feature that is already available in the legally marketed MedSystem III Infusion Pump. The DESK allows the user to access the factory default drug list in the infusion pump via the Field Maintenance Software (FMS). After access the user can add, modify, or delete drug names and dosing parameters. The modified list can then be downloaded into the MedSystem III Infusion Pump via the FMS. The FMS is already available as a legally marketed accessory to the MedSystem III Infusion Pump.

5. **INTENDED USE:** The intended use for the DESK is to allow users the ability to add, modify, or delete drug names and dosing parameters to the existing drug list for the Dose Rate Calculator feature in the MedSystem III Infusion Pump. The intended use for the MedSystem III Infusion Pump is to deliver a wide variety of fluids over a broad range of infusion rates, at high levels of accuracy.

6. TECHNOLOGICAL CHARACTERISTICS:

The MedSystem III Infusion Pump has not changed. The DESK is a software accessory with the same technological characteristics as the FMS software accessory.

The primary function of the MedSystem III Infusion Pump with or without the DESK is the same: to deliver a wide variety of fluids over a broad range of infusion rates. A similar feature to the DESK is already available in the legally marketed MedSystem III Infusion Pump. This feature allows the user to customize the drug list on a single basis. DESK allows the user to customize the drug list on a permanent basis. The technological characteristics of the devices are the same and raise no new questions of safety and effectiveness. IVAC Medical Systems, Inc. concludes that the MedSystem III Infusion Pump with or without the DESK are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 17 1998

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

Re: K961486
Trade Name: IVAC MedSystem III™, (MSIII) Infusion Pump with Drug Editing Software Kit, (DESK)
Regulatory Class: II
Product Code: MRZ
Dated: January 14, 1998
Received: January 20, 1998

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 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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" (21 CFR 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/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

IVAC
MEDICAL SYSTEMS

INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: MedSystem III Infusion Pump with Drug Editing Software Kit (DESK)

Indications for Use:

The intended use of the MedSystem III Infusion Pump is to deliver a wide variety of drugs and fluids (e.g., bloods, lipids, saline, dextrose) over a broad range of infusion rates, at high levels of accuracy. IVAC's policy is to not indicate specific drugs and/or fluids. Specific intended uses include enteral, intravenous, and epidural deliveries.

The Drug Editing Software Kit (DESK) allows the user to customize the resident drug list for the Dose Rate Calculator (DRC) feature that is available in the legally marketed MedSystem III Infusion Pump. The current system allows custom changes on a one by one basis. The DESK system allows users to make permanent custom changes to the resident drug list.

(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)

Patricia Cucuzzella
(Division Sign-Off)
(Division of Dental, Infection Control, and General Hospital Devices)

510(k) Number K961486

510(k) Number _____

5

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