DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 2001

Cynthia G. Royster
Director, Regulatory and Clinical Affairs
A-Med Systems, Inc.
2491 Boatman Avenue
West Sacramento, CA 95691

Re: K992592
Device Name: A-Med System's Miniature Centrifugal Blood Pump System
Regulatory Class: III
Product Code: KFM and DTQ
Dated: April 26, 2000
Received: April 30, 2001

Dear Ms. Royster:

This letter corrects our substantially equivalent letter of May 4, 2000 regarding the product code. Our letter identified the product code as KFM, however it should have also included DTQ as indicated above.

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.

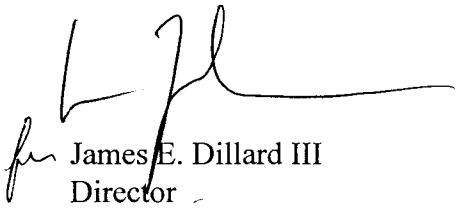
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General (QS) regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to

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 continue 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) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): K992592

Device Name: A-Med Miniature Centrifugal Pump System

Indications for Use:

The A-Med Miniature Centrifugal Blood Pump System is indicated for use in extracorporeal circulatory support systems (for periods up to six hours) not requiring artificial oxygenation (e.g., valvuloplasty, circulatory support during surgery of the vena cava or aorta, liver transplants, etc). The A-Med Miniature Centrifugal Blood Pump is indicated for use only with the A-Med Blood Pump Controller.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sign-Off)
of Cardiovascular, Respiratory
Neurological Devices
510(k) Number K992593

MAY - 4 2000

K992592

510(k) Summary of Safety and Effectiveness

This summary of 510(k)-safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Application Information:

Date Prepared:	February 14, 2000
Submitter:	A-Med Systems, Inc.
Address:	2491 Boatman Avenue West Sacramento, California, 95691
Contact Person:	Roberta L. Thompson Vice President, Clinical, Regulatory and Quality
Telephone Number:	(916) 375-7400 (extension 374)
Fax Number:	(916) 375-7444

Device Information:

Trade Name:	A-Med Miniature Centrifugal Pump System
Common Name:	A-Med Miniature Centrifugal Pump System

Classification Name: "Non-roller type Cardiopulmonary Bypass Blood Pumps" (21 CFR – 870.4360) "Blood Pump Speed Controllers" (21 CRF – 87.4380)

Predicate Devices:

Claim of Substantial Equivalence of the A-Med Miniature Centrifugal Pump System is made to:

Centrifugal Blood Pump

Medtronic Bio-Medicus BP-50 Centrifugal Pump (K852807)
Medtronic Bio-Medicus BPX-80 Bio-Pump (K973011)

Blood Pump Speed Controller

Medtronic Bio-Medicus Bio-Console Model 540 (K901584)
Sarns 7800 Centrifugal Pump Control Module (K950739)

Device Description:

The A-MED Miniature Centrifugal Pump is a sterile, disposable, non-pulsatile, non-roller pump which utilizes a rotor to impart energy to the blood through centrifugal forces. The flow of the miniature pump is "demand responsive" by automatically responding to the resistance against which it is pumping and to the amount of fluid returned to the miniature pump with the appropriate changes in flow and pressure. A drive cable and magnetic coupling are hermetically sealed components of the miniature pump.

The A-MED Miniature Centrifugal Pump System includes a motor, ultrasonic flow sensor and a microcomputer-based control console which are available separately. The Miniature pump consists of inner and outer housings containing a rotor which imparts energy to the pumping fluid through centrifugal forces. The inlet to the pump runs concentric with the axis of the rotor. The outlet of the pump is perpendicular to the inlet and tangent to the outer diameter. The shaft of the rotor is constrained by two sets of bearings that allow it to rotate freely. A lip seal is used just behind the rotor to seal fluid from entering into the bearing area.

A sheath cable assembly connects the pump to the drive motor. The pump end of the cable has a square drive shaft that is bonded and crimped to the cable. This drive shaft fits into a square opening in the end of the rotor. The other end of the cable is connected to a magnet rotor housed in a plastic shell. This end is assembled onto the motor-stator for operation. By assembling the magnet rotor into the end of the cable-sheath assembly, hermitic sealing of the pumping chamber is obtained.

A priming port (valve) is provided on the housing to clear the pump of air before starting circulation. The port is designed to open when a syringe is inserted and seals when the syringe is removed.

The pump is designed to be placed in the sterile field and operated from the A-Med remote motor and microcomputer based blood pump controller, located outside the sterile field. The A-Med Centrifugal Pump System also includes an ultrasonic flow meter, manufactured by Transonics, Inc.

Intended Use:

The A-Med Miniature Centrifugal Blood Pump System is indicated for use in extracorporeal circulatory support systems (for periods up to six hours) not requiring artificial oxygenation (e.g., valvuloplasty, circulatory support during surgery of the vena cava or aorta, liver transplants, etc). The A-Med Miniature Centrifugal Blood Pump is indicated for use only with the A-Med Blood Pump Controller.

Technological Characteristics:
This device has technological characteristics similar to the predicate devices.