K013393

NOV 0 9 2001

510(k) SUMMARY OF SAFETY & EFFECTIVENESS

This 510(k) Summary details sufficient information to provide an understanding of the basis for a determination of substantial equivalence. For convenience, the summary is formatted pursuant to 21 CFR §807.92. This section may be used, as presented, to provide a substantial equivalence summary to anyone requesting it from the Agency.

21 CFR §807.92 a (1)

Submitter: A-Med Systems, Inc
2491 Boatman Avenue
West Sacramento, CA 95691-3817
(916) 375-7400 ext. 5316
Contact person: Cynthia G. Royster
Date prepared: 11 October 2001

21 CFR §807.92 a (2)

Trade name: A-Med Heparin Coated Miniature Centrifugal Pump System

Common name: Centrifugal Pump
Classification name: "Non-roller type Cardiopulmonary Bypass Blood Pumps"870.4360

21 CFR §807.92 a (3)

Identification of predicate(s): Substantial equivalence for the A-Med Heparin Coated Miniature Centrifugal Pump is based on its similarities to the predicate devices, A-Med Miniature Centrifugal Blood Pump System (K992592). The modified *A-Med Heparin Coated Centrifugal Blood Pump* is substantially equivalent to the uncoated A-Med Miniature Centrifugal Blood Pump System in intended use, material, design, performance and physical characteristics. The modification adding heparin coating is the only change to the existing device.

21 CFR §807.92 a (4)

Device Description-parts and function/concept: The *A-Med Heparin Coated Miniature Centrifugal Blood Pump* is a sterile, disposable, non-pulsatile,

non-roller pump that utilizes an impeller to impart energy to the blood through centrifugal forces. The flow of the pump is "demand responsive" by automatically responding to the resistance against which it is pumping and to the amount of fluid returned to the large pump with the appropriate changes in flow and pressure. A drive cable and magnetic coupling are hermetically sealed components of the pump.

The coating which A-Med propose to add to the pump will be a photoactivated hydrogel surface modification. The process uses light activated chemistry to coat the device.

A motor ultrasonic flow sensor and a microcomputer-based control console are available separately.

21 CFR §807.92 a (5)

Intended use and relationship to predicate(s): The *A-Med Heparin Coated Miniature Centrifugal Blood Pump* 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 Heparin Coated Miniature Centrifugal Blood Pump* is indicated for use only with the A-Med Blood Pump Controller. The addition of the heparin coating does not impact the currently cleared indication for the existing device.

CFR §807.92 a (6)

Technological characteristics and relationship to predicate(s):
The *A-Med Heparin Coated Miniature Centrifugal Pump* is identical in design, material, intended use and technological characteristics to the uncoated predicate device. The difference between the two devices is the heparin coating only.

21 CFR §807.92 b

This substantial equivalence is based on similarities to the predicate device in terms of intended uses and technological characteristics.

21 CFR §807.92 c

In accordance with the specifications of this subsection, this summary (two pages) is its own section, and has been clearly identified as such.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 0 9 2001

Ms. Cynthia G. Royster
Director, Regulatory Affairs
A-Med Systems, Inc.
2491 Boatman Avenye
West Sacramento, CA 95691-3817

Re: K013393
Trade Name: A-Med Heparin Coated Minature Centrifugal Blood Pump
Regulation Number: 21 CFR 870.4360
Regulation Name: Nonroller-type cardiopulmonary bypass blood pump
Regulatory Class: II
Product Code: KFM
Dated: October 11, 2001
Received: October 15, 2001

Dear Ms. Royster:

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) 594-4586. 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,

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

Enclosure

NOV 0 9 2001

Indication Statement

K013393

Page ____ of ____

510(k) Number (if known): N/A

Device Name: *A-Med Heparin Coated Miniature Centrifugal Blood Pump*

Indications for Use

The *A-Med Heparin Coated 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 Heparin Coated 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)

Prescription Use_____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109) Optional Format 1-

Division of Cardiovascular & Respiratory Devices
510(k) Number K013393