

AUG 26 2002

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: 13 February 2002

21 CFR §807.92 a (2)

Trade name: A-Med Large Centrifugal Blood Pump

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 Large Centrifugal Blood Pump* is based on its similarities to the predicate devices, A-Med Miniature Centrifugal Blood Pump System (K992592) and Medtronic Bio-Medicus Centrifugal Blood Pump (K973011). The line extension *A-Med Large Centrifugal Blood Pump* is substantially equivalent to the predicates in intended use, material, design, performance and physical characteristics. The line extension included a larger motor to the existing larger housing to enable it to produce more pressure.

21 CFR §807.92 a (4)

Device Description-parts and function/concept: The *A-Med Large 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.

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 Large Centrifugal Blood Pump* is indicated for pumping blood through the extracorporeal bypass circuit for extracorporeal circulatory support for periods appropriate to cardiopulmonary bypass (up to six hours). It is also indicated for use in extracorporeal circulatory support systems (for periods up to six hours) not requiring complete cardiopulmonary bypass (e.g., valvuloplasty, circulatory support during mitral valve operations, surgery of the vena cava or aorta, liver transplants, etc). The *A-Med Large Centrifugal Blood Pump* is indicated for use only with the A-Med Blood Pump Controller.

CFR §807.92 a (6)

Technological characteristics and relationship to predicate(s):

The *A-Med Large Centrifugal Blood Pump* is identical in design, material, intended use and technological characteristics to the predicate devices. The difference is size and pressure only.

21 CFR §807.92 b

This substantial equivalence is based on similarities to the predicate devices 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.

Literature (cited)

1. Driessen JJ, Dhaese H, Fransen G, Verrelst P, Rondelez L, Gevaert L, van Becelaere M, Schelstraete E. "Pulsatile Compared with Nonpulsatile Perfusion Using a Centrifugal pump for Cardiopulmonary Bypass during Coronary Artery Bypass Grafting. Effect on Systemic Haemodynamics, Oxygenation, and Inflammatory Response Parameters", Perfusion 10 No. 1: 3-12 1995.
2. Glauber M, Szefer J, Senni M, Gamba A, Mamprin F, Fiocchi R, Somachini M, Ferrazzi P. "Reduction of Haemorrhagic Complications during Mechanically Assisted Circulation with the Use of a Multi-System Anticoagulation Protocol", Artificial Organs Vol. 18 No.10: 649-55 Oct. 1995.
3. Noon GP, Lafuente JA, Irwin S. " Acute and Temporary Ventricular Support with Bio-Medicus Centrifugal Pump", Ann Thorac Surg. Vol 68 2: 650-4.68 Aug 1999.
4. Ricardo Grossi Dantas, Eduardo Tavares Costa. "Ultrasonic Pulsed Doppler Blood Flowmeter for Use in Extracorporeal Circulation," Artificial Organs Vol. 24 No.3: 198-201 March 2000.
5. Takami Y, Makinouchi K, Nakazawa T, Benkowski R, Glueck J, Ohara Y, Nose Y. "Hemolytic characteristics of a Pivot Bearing Supported Gyro Centrifugal Pump (C1E3) Simulating Various Clinical Applications", Artif Organs Vol. 20 No.9: 1042-9 Sept. 1996.



AUG 26 2002

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K020529
Trade/Device Name: A-Med Large Centrifugal Blood Pump
Regulation Number: 21 CFR 870.4360
Regulation Name: Nonroller-type cardiopulmonary bypass blood pump.
Regulatory Class: Class III
Product Code: KFM
Dated: June 3, 2002
Received: June 21, 2002

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

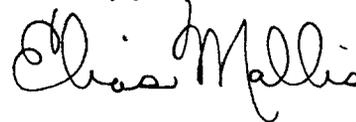
Page 2 - Ms. Cynthia G. Royster

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,



for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication Statement

Page ____ of ____

510(k) Number (if known): N/A K020529

Device Name: A-Med Large Centrifugal Blood Pump

Indications for Use

The *A-Med Large Centrifugal Blood Pump* is indicated for pumping blood through the extracorporeal bypass circuit for extracorporeal circulatory support for periods appropriate to cardiopulmonary bypass (up to six hours). It is also indicated for use in extracorporeal circulatory support systems (for periods up to six hours) not requiring complete cardiopulmonary bypass (e.g., valvuloplasty, circulatory support during mitral valve operations, surgery of the vena cava or aorta, liver transplants, etc). The *A-Med Large 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 X
Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter
Optional Format 1-

Elias Mallis

(Sign-Off)
Director of Cardiovascular
and Respiratory Devices

CONFIDENTIAL

510(k) Number K020529

7 of 101