K991541

510(k) Summary of Safety and Effectiveness

DEC 28 1999

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:	April 23, 1999
Submitter:	A-Med Systems, Inc.
Address:	2491 Boatman Avenue Sacramento, California, 95691
Contact Person:	Roberta L. Thompson Vice President, Clinical, Regulatory and Quality
Telephone Number:	(916) 375-7400 (extension 374)
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Device Information:

Trade Name:	A-Med Vascular Cannula
Common Name:	Vascular cannula
Classification Name:	"Cardiopulmonary Bypass Vascular Catheter, Cannula, or Tubing" (21 CFR 870.4210)

Predicate Devices:

Claim of Substantial Equivalence of the A-Med Vascular Cannula is made to the Baxter/RMI FEM FLEX II Cannula (K891576, K974259) manufactured by Baxter Healthcare Corporation Baxter Research Medical Inc., 6864 South 300 West, Midvale, UT 84047 USA.

Device Description:

The A-Med Vascular Cannula is a cannula comprised of a flexible tip, radiopaque stripes, wire reinforced tubing, non-reinforced proximal clamp zone, and a proximal connector. Configurations are available with the following options:

- Outer diameter: 24 French
- Effective length: 10, 21 inch
- Number of holes in tip: 8, 16, 32, 44 (dependant on length)
- Proximal connector: barb, barb with side luer lock, quick connect

Intended Use:

A-Med Vascular Cannula is intended for use in accessing the circulatory system during extracorporeal circulation.

Technological Characteristics:

This device has technological characteristics identical to the predicate device.

Nonclinical Performance:

The performance characteristics of this device were tested and compared with the performance characteristics of the currently marketed predicate device. In addition, performance characteristics of this device were tested and compared with A-Med Systems, Inc. performance specifications.

Clinical Performance:

Clinical testing was not performed on this device.

Conclusions from Nonclinical Tests:

The performance of this device is substantially equivalent to the predicate device and performs as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 28 1999

Ms. Roberta L. Thompson
Vice President
Clinical, Regulatory Affairs and Quality
A-Med Systems, Inc.
2491 Boatman Ave
West Sacramento, CA 95691

Re: K991541
A-Med Vascular Cannula
Modules V24-10-08,V24-10-16
Regulatory Class: II
Product Code: DWF
Dated: September 23, 1999
Received: September 29, 1999

Dear Ms. Thompson:

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 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 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,

Celia M. Witten, Ph.D., M.D.
Acting Director
Division of Cardiovascular
Respiratory and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): K991541

Device Name: A-Med Vascular Cannula, Models V24-10-08, V24-10-16

Indications for Use:

The A-Med Vascular Cannula is intended for intraoperative access to the arterial (i.e., aorta, femoral artery or pulmonary artery) or venous system, (i.e., femoral vein, right atrium) during procedures requiring arterial or venous access for short term extracorporeal support (less than six hours). Arterial or venous access is left to the discretion of the physician.

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K991541

(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-