K971105

JUL 11 1997

SECTION III

SAFETY AND EFFECTIVENESS SUMMARY

FOR THE AFFINITY

MYOTHERM™ XP CARDIOPLEGIA DELIVERY SYSTEM

The AVECOR MYOtherm™ XP Cardioplegia Delivery System is a device intended for the mixing, warming/cooling, and delivery of oxygenated blood/cardioplegia solution in a predetermined ratio. Blood/cardioplegia solution is delivered to the patient through the cardioplegia delivery system and appropriate cannula by the operation of a single occlusive roller pump.

SAFETY TESTING

Blood trauma was assessed by comparison of cellular damage during in vitro perfusion through the MYOtherm XP Cardioplegia Delivery System to the cell damage generated by the similar commercially available MYOtherm Cardioplegia Delivery System. The measurement of cellular depletion and hemolysis (plasma hemoglobin generation) was determined by utilizing fresh heparinized bovine blood circulated at specified constant flow rates for a six hour period. Cardioplegia delivery systems of each type were tested using in vitro test circuits. The test circuits with the MYOtherm systems were constructed as closely as possible to the test circuits containing the MYOtherm XP systems. Any differences in the design of the test circuits were due to differences between the MYOtherm and MYOtherm XP Cardioplegia Delivery Systems. A static pool of blood was simultaneously sampled with the test circuits to demonstrate acceptable hematologic parameters during the test period.

The cellular damage observed in the cardioplegia delivery systems were compared through T-tests to measure significant differences between the systems. Cellular damage to blood as measured by platelet and white blood cell depletion, (reported as a percentage of baseline values) and plasma hemoglobin generation (mg/dl) was not significantly different among the systems.

Material utilized in the production of the MYOtherm XP Cardioplegia Delivery System have been tested for biocompatibility and was found acceptable. The test results may be found in Section V of this submission.

EFFECTIVENESS INFORMATION

Effectiveness of the MYOtherm XP Cardioplegia Delivery System was determined by evaluating its operational characteristics as defined by the following tests:

- Heat exchanger performance
- Pressure drop
- Gross air management
- Structural integrity

Performance by the above testing shows that the MYOtherm XP Cardioplegia Delivery System is effective and meets all functional requirements of a cardioplegia delivery system.

Dennis E. Steger
Director Regulatory Affairs/
Quality Assurance

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 11 1997

Mr. Dennis E. Steger
Director Regulatory Affairs/
Quality Assurance
AVECOR Cardiovascular, Inc.
7611 Northland Drive
Minneapolis, Minnesota 55428

Re: K971105
Myotherm XP Cardioplegia Delivery System
Regulatory Class: II (Two)
Product Code: 74 DTN
Dated: April 11, 1997
Received: April 14, 1997

Dear Mr. Steger:

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 Current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS 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) 594-4648. 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,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

870.4400 - DTN II - CARDIOPLEGIA RESERVOIR

510(k) Number (if known): K971105

Device Name: MYOTHERM™ XP CARDIOPLEGIA DELIVERY SYS

Indications For Use:

The AVECOR MYOtherm™ XP Cardioplegia Delivery System is a device intended for the mixing, warming/cooling, and delivery of oxygenated blood/cardioplegia solution in a predetermined ratio. Blood/cardioplegia solution is delivered to the patient through the cardioplegia delivery system and appropriate cannula by the operation of a single occlusive roller pump.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number K971105

Prescription Use X OR Over-The-Counter Use
(Per 21 CFR 801.109)

(Optional Format 1-2-9