K965209

SECTION 2 - 510(k) SUMMARY and CERTIFICATION

JAN 23 1998

510(k) SUMMARY

This device is substantially equivalent to the following legally marketed intra-aortic balloon pumps:

1. The KAAT II Plus IABP catalog no. IAP-00025, from Arrow International, Everett, MA, Premarket Notification K905313.
2. The System 95 & 97 IABP, from Datascope Corporation, Paramus, NJ.
3. The TransAct H-8000 IABP, from C. R. Bard, Inc. Haverhill, MA.

The ACAT 1 IABP is the next generation of the Arrow/Kontron KAAT II Plus IABP manufactured by Arrow International. The ACAT 1 system is an advanced multi microprocessor based system that provides flexibility of operation and extended patient care capabilities, designed for in hospital and transport applications.

The ACAT 1 is a completely new industrial design package from the KAAT II Plus. Several new features have been incorporated which have continued to be customer requirements or preferences. The physical design of the ACAT 1 is smaller and lighter in weight than the current KAAT II Plus design. Overall we have incorporated new updates while maintaining the current product strengths of the KAAT II Plus system which are:

Unique lifetime metal bellows drive system
Wide range of triggering options
Continuous assessment/maintenance of helium
Safe alarming system
Calibrated, continuous usable Balloon Pressure Waveform
Cold trap, vapor removal system
Ease of use

The device is indicated for the following conditions:

Cardiogenic shock, Pre- shock syndrome, Post- infarction angina (Threatening extension of MI) Unstable refractory angina, or impending infraction, Ischemia related intractable ventricular dysrhythmias, Septic shock syndrome, Cardiac contusion, Support for diagnostic interventional procedures including: (Cardiac Angiography, Coronary Angioplasty (PTCA), Coronary Atherectomy, Failed Mitral Valvuloplasty), Mechanical complications due to acute myocardial infraction: (Valvular stenosis - Mitral stenosis, Mitral Valve insufficiency - Mitral regurgitation, Ventricular Septal Defect (VSD), Papillary muscle rupture), Prophylactic support in preparation for cardiac surgery or high risk cardiac patients undergoing non-cardiac surgical procedures, Post-surgical myocardial dysfunction , Cardiac support following correction of anatomical defects, Maintenance of graft patency post-coronary bypass surgery, Pulsatile flow during cardiopulmonary bypass, Mechanical bridge to other assist devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Michael Jesi
Manager, Regulatory Affairs
and Quality Assurance
Arrow International, Inc.
9 Plymouth Street
Everett, MA 02149

JAN 23 1998

Re: K965209
ACAT 1 (Arrow Cardiac Assist Technology 1)
Regulatory Class: II (Two)
Product Code: DSP
Dated: October 24, 1997
Received: October 27, 1997

Dear Mr. Jesi:

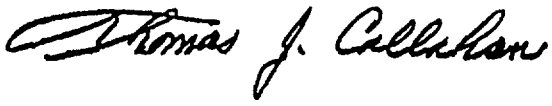
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 requirements, 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, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

870.3535 DSP III Intra-aortic Balloon and Control System

510(k) Number (if known): K965209

Indications for IABP use are as follows:

Cardiogenic shock
Pre- shock syndrome
Post- Infarction angina (Threatening extension of MI)
Unstable refractory angina, or impending infraction
Ischemia related intractable ventricular dysrhythmias
Septic shock syndrome
Cardiac contusion
Support for diagnostic interventional procedures including:
- Cardiac Angiography
- Coronary Angioplasty (PTCA)
- Coronary Atherectomy
- Failed Mitral Valvuloplasty

Mechanical complications due to acute myocardial infraction:
- Valvular stenosis - Mitral stenosis
- Mitral Valve insufficiency - Mitral regurgitation
- Ventricular Septal Defect (VSD)
- Papillary muscle rupture

Prophylactic support in preparation for cardiac surgery or high risk cardiac patients undergoing non cardiac surgical procedures
Post-surgical myocardial dysfunction
Cardiac support following correction of anatomical defects
Maintenance of graft patency post coronary bypass surgery
Pulsatile flow during cardiopulmonary bypass
Mechanical bridge to other assist devices.

(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 K965209

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)