

K 060309

Exhibit 1

APR 6 2006

ARROW
INTERNATIONAL

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION
as required by the Safe Medical Devices Act of 1990 and codified in
21 CFR 807.92 upon which the substantial equivalence is based.

9 Plymouth Street
Everett, MA 02149

AutoCAT Series IAPB Series
Date Prepared: February 3, 2006

(617) 389-6400
FAX: (617) 387-2157

A. Submitter's Name:

Arrow International
9 Plymouth Street
Everett, MA 02149

B. Company Contact

Karen Provencher
Senior Regulatory Affairs Specialist
Phone 617-389-6400, fax 601-387-2157

C. Device Name

| | |
|----------------------|---|
| Trade Name: | AutoCAT IABP Series |
| Common Name: | Intra-Aortic Balloon Pump (IABP) |
| Classification Name: | Intra-Aortic Balloon and Control System |

D. Predicate Devices

Arrow International AutoCAT Series IABP System represents the integration of four Arrow IABP technologies which is substantially equivalent in Intended Use and Fundamental Scientific Technology to the following legally marketed device in commercial distribution:

- AutoCAT, cleared in K983866, (1/6/00)
- ACAT 1, cleared in K965209, (1/23/98)
- ACAT 2, cleared in K002256, (5/3/01)
- FOS / FOMS IAB Black Box, cleared in K021462, (6/6/02)

E. Description of Device

The Intra-Aortic Balloon Pump (IABP) provides cardiac assist therapy. The IABP provides temporary support to patients with impaired left ventricular function through the therapeutic method referred to as counterpulsation. Counterpulsation increases coronary and systemic perfusion, decreasing after load (myocardial work) and decreasing preload.

The AutoCAT Series IABP System utilizes computer technology to select and maintain precise IAB inflation and deflation timing and triggering based on current physiological data from the patient. The system offers two modes of operation, the Autopilot mode, where functions are automatically selected and controlled by the IABP and the Operator mode where the user has control over settings and selections.

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F. Intended Use

The pump is medically indicated for use in any of the following conditions: Refractory Left Ventricular Failure, Cardiogenic Shock, Septic Shock, Pre-Shock Syndrome, Post Infarction Angina or Threatening Extension of Myocardial Infarction, Unstable (refractory) angina, Impending Infarction, Ischemia Related Ventricular Arrhythmia, Cardiac Contusion, Support and stabilization of High Risk Patients undergoing Diagnostic and non-surgical procedures: Cardiac Angiography, Coronary Angioplasty (PTCA), Coronary Atherectomy, Thrombolytic Therapy, and Failed Mitral Valvuloplasty. Mechanical complications due to Acute Myocardial Infarction: Valvular Stenosis (Mitral), Valvular Insufficiency (Mitral regurgitation), Ventricular Septal Defect (VSD), and Papillary Muscle Rupture. Prophylactic support in preparation for cardiac surgery or high risk cardiac patients undergoing non cardiac surgical procedures, Prophylactic Support (Preparation) for Cardiac Surgery, Weaning for Cardiopulmonary Bypass, Intra-operative pulsatile flow generation, Post Surgical Myocardial Dysfunction, Cardiac Support following correction of anatomical defects, Maintenance of graft patency post coronary artery bypass surgery, and Mechanical bridge to other assist devices

G. Comparison of Technological Characteristics

The modified Software V2.22 features the modifications to the following - Clarification / Modification to Pre-set Start-up Settings, General Improvements in AutoPilot Timing, Modifications to AP Zero and Calibration Function, Improvements in AutoPilot Signal Switching & Selection, General Improvements in Triggering, Improved Purge Cycle & Helium Refill Function, Recognition of IAB Connector Volumes, Improved Noise Recognition and Handling, Modifications to Arrhythmia Timing Function, Alarm Handling Improvements, Additions to Help Text, Activation of Modem Function, Regular Output of RS232

H. Summary Performance Data

The AutoCAT IABP Series with modified software meets all the same performance standards of the unmodified device including the following:

1. FDA Guidance: "Guidance for the Preparation and Content of Applications to the Food and Drug Administration for Determining the Equivalence of Intra-Aortic Balloon Catheters and Consoles under the 510(k) Regulations - Preliminary Draft, December.8, 1993
2. FDA Guidance: "General Principles of Software Validation – Final Guidance" January 11, 2002
3. FDA Guidance: "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices - Final Guidance" May 11, 2005
4. IEC 60601-1-4:1997: Medical Electrical Equipment – General Requirements for Safety – Collateral Standard: Programmable Electrical Medical Systems
5. EN 55024:1998: Information Technology Equipment – Immunity Characteristics
6. EN 55022:1998: Information Technology Equipment – Radio Disturbance Characteristics Limits and Methods of Measurement



APR 6 2006

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Arrow International, Inc.
c/o Ms. Karen Provencher
Senior Regulatory Affairs Specialist
9 Plymouth Street
Everett, MA 02149

Re: K060309

Arrow AutoCAT Intra-Aortic Balloon Pump (IABP) Series
Regulation Number: 21 CFR 870.3535
Regulation Name: Balloon, Intra-Aortic and Control System
Regulatory Class: Class III
Product Code: DSP
Dated: March 17, 2006
Received: March 23, 2006

Dear Ms. Provencher:

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.

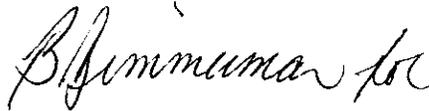
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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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), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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/industry/support/index.html>.

Sincerely yours,



Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Exhibit 2

Indications for Use

510(k) Number (if known): _____

K060309

Device Name: AutoCAT Intra-Aortic Balloon Pump (IABP) Series

Indications For Use:

The pump is medically indicated for use in any of the following conditions:

Refractory Left Ventricular Failure

Cardiogenic Shock

Septic Shock

Pre-Shock Syndrome

Post Infarction Angina or Threatening Extension of Myocardial Infarction

Unstable (refractory) angina

Impending Infarction

Ischemia Related Ventricular Arrhythmia

Cardiac Contusion

Support and stabilization of High Risk Patients undergoing Diagnostic and non-surgical procedures

Cardiac Angiography

Coronary Angioplasty (PTCA)

Coronary Atherectomy

Thrombolytic Therapy

Failed Mitral Valvuloplasty

Mechanical complications due to Acute Myocardial Infarction

Valvular Stenosis (Mitral)

Valvular 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

Prophylactic Support (Preparation) for Cardiac Surgery

Weaning for Cardiopulmonary Bypass

Intra-operative pulsatile flow generation

Post Surgical Myocardial Dysfunction

Cardiac Support following correction of anatomical defects

Maintenance of graft patency post coronary artery bypass surgery

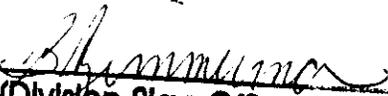
Mechanical bridge to other assist devices

Prescription Use X OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

(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 Devices
510(k) Number K060309

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