Section 5 – 510(k) Summary

a. Submitted

Arrow International, Inc.
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Date summary prepared: 01/30/01

b. Device

Trade Name: RediGuard® 9Fr. Universal Intra-Aortic Balloon Catheter
Common Name: Intra-aortic balloon catheter
Classification Name: Balloon, intra-aortic and control system

c. Legally marketed device to which the device is substantially equivalent

The device is substantially equivalent to the current legally marketed Arrow RediGuard® 9Fr. 40cc and the Arrow 10Fr. 50cc IABs with a tear away hemostasis device.

d. Description of device

The device is a dual lumen percutaneously inserted Intra-Aortic IAB catheter, 9 Fr. in size, with two independent non-communicating lumens. The outer lumen is comprised of an inflatable bladder connected to the catheter distal tip and to the IAB tip outer surface. The inner lumen is comprised of a luer adapter connected to the proximal end of the inner lumen and to the IAB tip inner surface. The IAB inner lumen is used for placement of the device with a guidewire and the outer lumen is used to shuttle helium gas to and from the inflatable bladder. The IAB is timed to inflate in the aorta during the diastolic relaxation of the heart and deflate during the systolic contraction of the heart, resulting in increased blood supply to the heart muscle and decreased work load for the left ventricle.

The Arrow RediGuard® catheter is available in a 9Fr. 50cc volume, and is identical in appearance and function to the predicate devices.

e. Intended use of the device

The IAB is utilized for intra-aortic balloon counterpulsation therapy. The balloon inflation in the aorta during diastole and deflation during systole which increases the blood supply to the heart muscle and decreases work of the left ventricle.

f. Technological characteristics

The device has the same similar technological characteristics as its predicates.

The results of the laboratory tests demonstrate that the device is safe, and as effective as the cleared predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 2 2001

ARROW International
c/o Mr. William Paquin
QA/RA Manager
9 Plymouth Street
Everett, MA 02149

Re: K010330
Trade Name: Arrow RediGuard® 9Fr. 50cc Universal Intra-Aortic Balloon Catheters
Regulatory Class: III (three)
Product Code: DSP
Dated: January 30, 2001
Received: February 02, 2001

Dear Mr. Paquin:

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 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" (21CFR 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/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K010330

Arrow International, Inc.
9 Plymouth Street
Everett, MA 02149

Section 6 – Indications for use

Device name: Arrow RediGuard® 9 Fr. 50cc Universal Intra-Aortic Balloon Catheters.

Indications for use: Refractory left ventricular heart failure. Cardiogenic shock. Unstable refractory angina. Mechanical complication due to acute myocardial infarction; i.e. ventricular septal defect, mitral regurgitation or papillary muscle rupture. Impending infarction. Ischemia related intractable ventricular arrhythmia. Septic shock. Support for failed angioplasty and valvuloplasty. Cardiac support for high risk general surgical patients.

3/2/1

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

510(k) Number K010330