K970689

JUN 4 1998

SECTION 2 - 510(k) SUMMARY and CERTIFICATION

510(k) SUMMARY

The addition of a new peel-away hemostasis device to four existing Arrow IABs makes them now "universal" IABs, in that they can be used as is for sheathless insertion techniques, or can be used with current standard sheaths if the sheathless feature is not desired, by peeling it away and discarding it.

The four new "Universal" products are therefore substantially equivalent to eight current Arrow IAB products.

The device new "Universal" are indicated for the following conditions:

Refractory left ventricular power failure. Cardiogenic shock unstable refractory angina. mechanical complication due to acute myocardial infraction; i.e., ventricular sepial defect mitral regurgitation or papillary muscle rupture. Impending infraction, ischemia related intractable ventricular arrhythmias. Septic shock. Support for failed angioplasty and valvuloplasty. Cardiac support for high risk general surgical patients.

The devices have comparable technological characteristics to the predicate devices.

The nonclinical performance test results included in the submission show comparable performance to the predicate sheathless devices.

CERTIFICATION

Since this is a class III device, the required class III Special Certification is appended as Attachment 1.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

JUN 4 1998

Mr. Robert A. Szurgot
Project Engineer
Arrow International
Research/Engineering
3000 Bernville Road
Reading, Pennsylvania 19605

Re: K970689
Arrow Intra-Aortic Balloon Catheter with Peel-Away Hemostasis Device (IAB-04840-U; IAB-04250-U; IAB-04240-U; IAB-04230-U)
Regulatory Class: III (Three)
Product Code: 74 DSP
Dated: June 6, 1997
Received: June 11, 1997

Dear Mr. Szurgot:

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

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 Syste

510(k) Number (if known): K970689

Device Name: Arrow Intra-Aortic Balloon Catheter with Peel-Away Hemostasis Device IAB-04840-U IAB-04240-U IAB-04230-U

Indications For Use:

Refractory left ventricular power failure. Cardiogenic shock, unstable refractory angina. Mechanical complication due to acute myocardial infraction; i.e., ventricular septal defect, mitral regurgitation or papillary muscle rupture. Impending infraction, ischemia related intractable ventricular arrhythmias. Septic shock. Support for failed angioplasty and valvuloplasty. Cardiac support for high risk general surgical patients.

(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 K970689

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

(Optional Format 1-2-96)