K963920

JUN 17 1997

510(k) SUMMARY - K963920

The device is substantially equivalent to the following legally marketed Arrow intra-aortic balloon devices:

1. 8 Fr-40cc NarrowFlex™, with Nitinol inner lumen and kink resistant outer lumen, product no. IAB-04840, premarket notification K960713.
2. 8 Fr-30cc, with stainless steel inner lumen and plastic outer lumen, product no. IAB-04230, premarket notification K892799.

This device is identical in construction to the predicate 8 Fr-40cc NarrowFlex™ device IAB-04840 with the exception of the 30cc balloon and shorter overall length. The balloon volume and the overall length have been adapted from the 8 Fr-30cc IAB-04230 predicate.

The device is 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 device has comparable technological characteristics to the predicate devices.

The nonclinical test results included in the submission showing comparable performance to the predicate devices are as follows:

Performance Test
- Total cycle time
- Displaced volume
- First response

96123

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 17 1997

Mr. Thomas D. Nickel
Vice President, Regulatory Affairs
and Quality Assurance
Arrow Intenational, Inc.
3000 Bernville Road
Reading, Pennsylvania 19605

Re: K963920
Arrow 8 Fr. - 30cc Narrowflex™ Intra-Aortic Balloon Catheter
Regulatory Class: III (Three)
Product Code: 74 DSP
Dated: January 14, 1997
Received: January 17, 1997

Dear Mr. Nickel:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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"dsmo@fdadr.cdrh.fda.gov."

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

510(k) Number (if known): K963920

Device Name: Arrowflex 8Fr 30cc Neuroflex™

P.O. Box 12888
Reading, PA 19612

ARROW INTERNATIONAL

3000 Bernville Road
Reading, PA 19605

(610) 378-0131
FAX: (610) 374-5360

Section 11 - Indications

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.

(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 K963920

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use___

(Optional Format 1-2-96)