DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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June 16, 2016

Arrow International, Inc.
c/o Mr. William Paquin
Quality Assurance/Regulatory Affairs Manager
9 Plymouth Street
Everett, MA 02149

Re: K010330
Trade/Device Name: Arrow Rediguard® 9Fr. 50cc Intra-Aortic Balloon Catheters IAB-R950-U
Regulation Number: 21 CFR 870.3535
Regulation Name: Intra-aortic balloon and control system
Regulatory Class: Class II
Product Code: DSP
Dated: January 30, 2001
Received: February 2, 2001

Dear William Paquin:

This letter corrects our substantially equivalent letter of March 2, 2001.

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Eric E. Richardson -S

For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K010330

Device Name
Arrow Rediguard® 9Fr. 50cc Intra-Aortic Balloon Catheters IAB-R950-U

Indications for Use *(Describe)*
The Arrow Rediguard® 9Fr. 50cc Intra-Aortic Balloon Catheters IAB-R950-U is clinically indicated for the following conditions:
a. Acute Coronary Syndrome
b. Cardiac and Non-Cardiac Surgery
c. Complications of Heart Failure

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K010330

Teleflex®

Arrow International, Inc

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510(k) Summary K010330

Arrow Rediguard, 9FR. 50CC, Intra-Aortic Balloon Catheter, IAB-R950-U

Date Prepared: January 30, 2001
Date Summary Updated: July 28, 2015

A. Submitter's Name:

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

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C. Device Name

Trade Name:	Arrow RediGuard® 9Fr. 50 cc Intra-Aortic Balloon Catheters IAB-R950-U
Common Name:	Intra-aortic balloon catheter
Classification Name:	Balloon, Intra-Aortic and Control System

D. Predicate Devices

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.

E. 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 arid 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.

F. Indications for Use

The Arrow RediGuard® 9Fr. 50cc Intra-Aortic Balloon Catheters IAB-R950-U is clinically indicated for the following conditions:

a. Acute Coronary Syndrome
b. Cardiac and Non-Cardiac Surgery
c. Complications of Heart Failure

G. Technological Characteristics

The device has similar technological characteristics as its predicates.

The results of the laboratory tests demonstrate that the device is substantially equivalent to the cleared predicate devices.