August 4, 2022

Arrow Intl., Inc.
William Paquin
Quality Assurance/Regulatory Affairs
9 Plymouth St.
Everett, Massachusetts 02149

Re: K002256
Trade/Device Name: Arrow ACAT 2 Intra-Aortic Balloon Pump
Regulation Number: 21 CFR 870.3535
Regulation Name: Intra-aortic balloon and control system
Regulatory Class: Class II
Product Code: DSP

Dear William Paquin:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated dated May 3, 2001. Specifically, FDA is updating this SE Letter to reflect an administrative correction corresponding to the reclassification of intra-aortic balloon and control system (IABP) devices when indicated for acute coronary syndrome, cardiac and non-cardiac surgery, or complications of heart failure, a preamendments class III device, into class II (special controls), as detailed in the final order published on December 20, 2019 (see here for more information: https://www.federalregister.gov/documents/2013/12/30/2013-31218/cardiovascular-devices-reclassification-of-intra-aortic-balloon-and-control-systems-for-acute#:~:text=The%20Food%20and%20Drug%20Administration%20(FDA)%20is%20issuing%20a%20final,(special%20controls)%2C%20and%20to). In addition, IABP devices indicated for septic shock or pulsatile flow generation will remain Class III devices and would not be appropriate for the premarket notification pathway(510(k)), instead requiring a premarket approval (PMA).

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Alejandra Cambonchi, OHT2: Office of Cardiovascular Devices, 301-796-0552, Alejandra.Cambonchi@fda.hhs.gov.

Sincerely,

Nicole M. Gillette -S

Nicole Gillette
Assistant Director
DHT2B: Division of Circulatory Support,
Structural and Vascular Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 3 2001

ARROW INTERNATIONAL, INC.
c/o Mr. William Paquin
Quality Assurance/Regulatory Affairs Manager
9 Plymouth Street
Everett, MA 02149

Re: K002256
Trade Name: ARROW ACAT 2 INTRA-AORTIC BALLOON PUMP
Regulatory Class: III (three)
Product Code: DSP
Dated: January 30, 2001
Received: February 2, 2001

Dear Mr. Paquin:

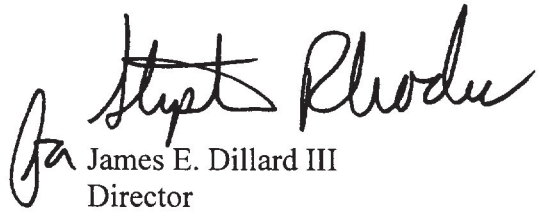
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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,



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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K002256

Device Name
Arrow ACAT 2 Intra-Aortic Balloon Pump

Indications for Use *(Describe)*

The ACAT 2 Intra-Aortic Balloon Pump 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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Arrow International LLC
(Subsidiary of Teleflex Inc.)
3015 Carrington Mill Blvd
Morrisville, NC 27560

510(k) Summary K002256

Arrow ACAT 2 Intra-Aortic Balloon Pump

Date Prepared: May 23, 2001
Date Summary Updated: July 27, 2022

A. Submitter

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

Updated Correspondent Address:
Arrow International LLC
(Subsidiary of Teleflex Inc.)
3015 Carrington Mill Blvd
Morrisville, NC 27560

B. Contact Person

Brenda Johnson, Director of Regulatory
Phone: 612-263-2065

C. Device Name

Trade Name:	Arrow ACAT 2 Intra-Aortic Balloon Pump
Common Name:	Intra-Aortic Balloon Pump (IABP)
Classification Name:	Intra-Aortic Balloon and Control System (21 CFR 870.3535)

D. Predicate Devices

The ACAT 2 is substantially equivalent to the following devices:

1. Belmont Model NGPBP IABP, Belmont Instruments Corporation (K983866)
2. ACAT 1, Arrow International (K965209)
3. KAAT II Plus IABP, Arrow International (K905313)
4. System 95 and 97 IABP, Datascope Corporation (K942454, K961509)
5. Bard Transact System H8000, Belmont Instruments Corporation (K915580)

E. Description of Device

The ACAT 2 IABP is the next generation of the Arrow ACAT 1 IABP manufactured by Arrow International.

The purpose of the new ACAT 2 is to convert the original ACAT 1, which is a manual adjustment system, into a one button automatic or manual IABP system. This will be accomplished through the development of new software algorithms. The existing ACAT 1 hardware, electronics, pump assembly and packaging designs are the same for the ACAT 2 IABP.

NOTE: This is a software update to the existing ACAT 1 IABP only.

This software has been developed to meet customer requirements and/or preferences. The software is identical to the ACAT 11 software, with the addition of an “Optimized” mode. The Optimized mode employs greater device involvement in detecting the patient’s heartbeat and timing the inflation and deflation of the Intra-Aortic Balloon (IAB), thus reducing the requirements for intense monitoring by a qualified Cardiologist or Perfusionist.

F. Indications for Use

The Arrow ACAT 2 Intra-Aortic Balloon Pump 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 comparable technological characteristics as its predicates.