DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 31, 2017

Arrow International, Inc.
Alifiya Jagmag
Manager, Regulatory Affairs
16 Elizabeth Dr.
Chelmsford, Massachusetts 01824

Re: K162820
Trade/Device Name: AC3 Series IABP System
Regulation Number: 21 CFR 870.3535
Regulation Name: Intra-Aortic Balloon and Control System
Regulatory Class: Class II
Product Code: DSP
Dated: March 3, 2017
Received: March 6, 2017

Dear Alifiya Jagmag:

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" (21 CFR 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,

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)*
K162820

Device Name
AC3™ Series IABP System

Indications for Use *(Describe)*

The AC3™ Series IABP (Intra-Aortic Balloon Pump) System 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.

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Section 5- 510(k) Summary

5.1 Statement

This 510(k) summary is being submitted in accordance with the requirements of Safe Medical Device Act (SMDA) 1990 and CFR 807.92.

5.2 Submitter

Arrow International, Inc. (Subsidiary of Teleflex, Inc.)
16 Elizabeth Drive
Chelmsford, MA 01824
Establishment Registration: 3010532612
Arrow International, Inc. (Subsidiary of Teleflex, Inc.)
Reading, PA 19605:
Owner/ Operator: 2518433

5.3 Company Contact

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Date Prepared: 30 March 2017

5.4 Device Name

Proprietary Name: AC3™ Series IABP System
Common Name: Intra-Aortic Balloon Control System
Classification Name: Intra-aortic balloon and control system (21 CFR 870.3535), Regulatory Class: II, Product Code: DSP

5.5 Predicate Legally Marketed Devices

The AC3 Series Intra-Aortic Balloon Pump (IABP) System, which is the subject of this submission, is substantially equivalent to the previously cleared Arrow AutoCAT®2 IABP System which was previously cleared via K060309.

5.6 Device Description

The AC3 Series IABP System is the next generation platform which is based on the existing AutoCAT2 IABP System; cleared via K060309 on 6 April 2006.

The AC3 Series IABP System (AutoCAT3) includes a new Graphical User Interface. The primary algorithms that control the therapeutic function of the device have not been altered from the AutoCAT2.

This premarket notification is applicable to the following part numbers:
Versions utilizing the Fiber Optic Sensor (FOS) or WAVE (Wind Kessel Aortic Valve Equation) capabilities:

- IAP-0700 AC3 Optimus™ IABP
- IAP-0701 AC3 Optimus™ IABP

Versions without the FOS or WAVE capabilities:

- IAP-0600 AC3™ IABP
- IAP-0601 AC3™ IABP

Note: The 01 ending indicates physical language labeling only. The part numbers IAP-0700 and IAP-0600 include the North American (NA) and European (EU) languages and the part numbers IAP-0701 and IAP-0601 include the NA, Asia, Japan and Latin America (AJLA) languages. All the part numbers will be commercially released OUS (outside of United States of America) after respective country registrations have been received. Functionally all the above mentioned part numbers are equivalent in performance and specifications.

System Description:
The AC3 Series IABP system provides counter-pulsation therapy to adult patients with impaired Left Ventricular (LV) Function. It provides hemodynamic support of blood pressure and reduced cardiac work through volume displacement principles. The IABP is attached to an IAB (Intra-aortic Balloon) catheter which is inserted into the femoral artery and positioned in the descending thoracic aorta.

The IABP delivers Helium (HE) into the IAB during diastole to displace blood above and below the IAB, increasing blood pressure and perfusion to organs close to the IAB catheter. The

IABP deflates or removes HE from the IAB just prior to or in the early phase of systole, reducing the pressure in the aorta and therefore the pressure the LV must generate to open the aortic valve and eject its contents into the circulatory system. This results in a decrease in work and oxygen demand.

The AC3 Series IABP System consists of two main components:

- The pump control / display module which incorporates a touch screen and keypad for system operation
- The pneumatic drive module which is incorporated into the body of the device.

The AC3 is designed to be used with 30, 35, 40, and 50cc Intra-Aortic Balloons with the appropriate connectors. (UltraFlex™, Ultra 8®, NarrowFlex®, and RediGuard® Catheters).

The system offers two modes of operation:

- Autopilot Mode, where most functions are automatically selected and controlled by the IABP
- Operator mode, where an operator can control most settings and selections.

5.7 Device Indications and Intended use

Indications For Use:

The AC3 IABP (Intra-Aortic Balloon Pump) System is clinically indicated for the following conditions:

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

5.8 Performance Testing

Extensive performance testing has been completed to demonstrate that the AC3 is substantially equivalent to the AutoCAT2 device previously cleared via K060309.

Following is a summary of the testing that has been completed to demonstrate substantial equivalence.

Electrical Safety and Electromagnetic Compatibility Testing

Electrical Safety and Compliance testing was conducted by an outside test house.

Test reports provided confirm that the AC3 is in compliance with the standards as noted in Table 5.1 below.

Table 5.1: IEC Standards Applicable to the AC3 IABP

Standard	Description
IEC 60601-1 3rd edition	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2 3rd edition	Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests
IEC 60601-1-6 3rd edition	Medical Electrical Equipment - Part 1-6: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Usability
IEC 60606-1-8 2nd edition	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
IEC 60601-2-27 3rd edition	Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment

Standard	Description
IEC 60601-2-34 3rd edition	Medical electrical equipment. Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment
IEC 60601-2-49 2nd edition	Medical electrical equipment. Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment
RTCA DO-160 Section 20 Category R	Radio Frequency Susceptibility (Conducted and Radiated)
N/A	Design Considerations for Devices Intended for Home Use Guidance Document

Software Verification Testing

The software has been developed in accordance with IEC 62304:2006, Medical device software-Software lifecycle processes. Software Verification testing has been completed to demonstrate that the software requirements have been met. Documentation has been supplied to also comply with FDA's guidance document, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".

Human Factors Testing / Usability Testing

Testing was completed to demonstrate that the changes to the user interface did not negatively impact the performance of the device. Testing was completed in accordance with FDA's Final Guidance document, *Applying Human Factors and Usability Engineering to Medical Devices* and in accordance with IEC 62366:2007.

As part of this evaluation 33 users participated in the evaluation. Each participant was asked to perform 22 uses cases that were developed based on critical tasks and areas for potential risk due to potential use errors. There were no use errors observed during testing and 96% of the use cases were completed successfully with no operational difficulty (on the first attempt) whereas 4% of the use cases were completed with only minor operational difficulty.

Cleaning and Disinfection

Cleaning: A study was conducted by an outside test house in accordance with the following recognized standards:

- AAMI TIR12:2010 – Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities.
- AAMI TIR30:2011 – A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices, and Reprocessing Medical Devices in Health Care Settings

Testing was completed to verify the effectiveness of the recommended cleaning methods. Components of the device that represented the worst case based on the material and the use profile of the components were selected for inclusion in the protocol..

Disinfection: Testing was also completed to demonstrate the recommended method of disinfection would result in a six $\log_{10}$ reduction in colony forming units (CFU) of selected organisms. Testing was completed in accordance with the following recognized standards:

- AAMI TIR12:2010 – Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities.
- ANSI/AAMI ST58:2013 – Chemical sterilization and high-level disinfection in health care facilities, and Reprocessing Medical Devices in Health Care Settings.

Testing demonstrated the AC3 Series IABP system could effectively be cleaned and disinfected using the recommended methods.

Environmental/ Mechanical Testing

Mechanical design verification testing was conducted to confirm that the AC3 Series IABP System meets all requirements with respect to operational parameters and reliability and is substantially equivalent to the predicate device, AutoCAT2 IABP. The result of this testing confirms that the device meets all acceptance criteria and specifications as required.

Design Validation Testing

ECG trigger validation Testing was conducted using recordings of real Electro-Cardiogram (ECG) waveforms from the American Heart Association (AHA) database to confirm that the AC3 Series IABP system ECG Triggering was equivalent to the AutoCAT2 ECG Triggering. As part of this testing an AutoCAT2 and AC3

Series IABP system were simultaneously assessed using the same ECG input. The data confirmed that the devices are substantially equivalent with regard to their triggering reliability.

Reliability testing was also completed to confirm that the AC3 Series IABP system could run continuously and perform as intended. As part of this test AC3 pumps were run continuously for 9 days; from 216 to 218 hours. All pumps successfully inflated and deflated the attached IAB catheter and met all acceptance criteria for this test.

Rate limit testing was completed to verify that the AC3 Series IABP system was able to successfully inflate and deflate the various size IAB catheters i.e. 30cc, 35cc, 40cc and 50cc that were connected to the IABP system. Testing confirmed that the inflation and deflation of connected balloons met all requirements.

Table 5.2 provides a comparison of the AutoCAT2 IABP cleared via K060309 and the AC3 Series IABP system that is the subject of this submission.

Table 5.2: Table of Substantial Equivalence

Attribute	AutoCAT2 Series IABP (Predicate Device)	AC3 Series IABP system (Subject Device)	Comparison
Indications for Use	The AutoCAT2 Intra-Aortic Balloon Pump (IABP) is clinically indicated for the following conditions: a. Acute Coronary Syndrome b. Cardiac and Non-Cardiac Surgery c. Complications of Heart Failure	The AC3 Series Intra-Aortic Balloon Pump (IABP) System is clinically indicated for the following conditions: a. Acute Coronary Syndrome b. Cardiac and Non-Cardiac Surgery c. Complications of Heart Failure	No change. Same as AutoCAT2
Intended Use	The AutoCAT2 IABP is intended to provide counter-pulsation therapy to adult patients with impaired Left ventricular function. The users consist of trained hospital personnel in Intensive care areas, Cardiac Cath Labs, Cardiac Operating Rooms and emergency departments. This device is for in-hospital use and for transport between departments in a specific hospital or between facilities as required by the patient condition and treatment required.	The AC3 Series IABP system is intended to provide counter-pulsation therapy to adult patients with impaired Left ventricular function. The users consist of trained hospital personnel in Intensive care areas, Cardiac Cath Labs, Cardiac Operating Rooms and emergency departments. This device is for in-hospital use and for transport between departments in a specific hospital or between facilities as required by the patient condition and treatment required.	No change. Same as AutoCAT2
Compatible Disposable	30, 35, 40, and 50cc Intra-aortic balloons	30, 35, 40, and 50cc Intra-aortic balloons	No change. Same as

Attribute	AutoCAT2 Series IABP (Predicate Device)	AC3 Series IABP system (Subject Device)	Comparison
Sets	marked with Arrow	marked with Arrow	AutoCAT2
Sterility	Non-sterile	Non-sterile	No change. Same as AutoCAT2
Environmental Specifications	Operating Temperature: 5°C to 45°C (without Fiber Optic Sensor) 5°C to 35°C (with Fiber Optic Sensor) Specification Storage and transport Temperature: -15°C to 40°C Storage and transport Atmospheric Pressure: 200 hPa - 1060 hPa (150mmHg - 796mmHg) Storage and Transport Humidity: 15% - 80%	Operating Temperature: 0°C to 45°C (without Fiber Optic Sensor) 0°C to 35°C (with Fiber Optic Sensor) Specification Storage and transport Temperature: -15°C to 40°C Storage and transport Atmospheric Pressure: 200 hPa - 1060 hPa (150mmHg - 796mmHg) Storage and Transport Humidity: 15% - 85%	Greater range of operating temperature and storage and transport humidity conditions all other specifications remains the same.
Performance Specifications	Stepper motor driven bellows pneumatic system with augmented deflation and no disposable parts. Pumping volume: 0.5cc – 50cc, adjustable in 0.5cc increments	Stepper motor driven bellows pneumatic system with augmented deflation and no disposable parts. Pumping volume: 0.5cc – 50cc, adjustable in 0.5cc increments	No change. Same as AutoCAT2
	Sealed Lead Acid battery (minimum of 90 minutes) with an optional battery upgrade to double battery life.	Sealed Lead Acid battery (minimum of 90 minutes) with an optional battery upgrade to double battery life.	No change. Same as AutoCAT2
	Power supply 85 to 265V 47 to 63Hz Power consumption 225W or 3.1A	Power supply 85 to 265V 47 to 63Hz Power consumption 110V- 5.1A 220V- 2.8A	New power supply which has the same functional and performance

Attribute	AutoCAT2 Series IABP (Predicate Device)	AC3 Series IABP system (Subject Device)	Comparison
	Universal Power Supply	Universal Power Supply	specifications.
Display	10.3 Inch Color LCD display. 26 Hard keys available for all functions. No touch screen.	13.3 Inch High Resolution touchscreen display 6 hard keys for frequently used or safety functions.	AC3 Series IABP system has a larger, high resolution touchscreen with an improved user interface
	Hard keys are backlit LEDs for selection.	Hard keys and text are both backlit LEDs and color coded	Improved visibility of keys in dark
	No Alarm indication corner switch	AC3 Display head has a color coded corner switch that illuminates when an alarm is active.	The Corner switch acts as a visual indicator for the priority of alarm and also allows the user to reset alarm.
Operational Modes	2 Operational Modes: Autopilot and Operator mode	2 Operational Modes: Autopilot and Operator mode	No change. Same as AutoCAT2
	Autopilot mode Includes: • Automatic trigger selection • Automatic ECG/Arterial Pressure (AP) source selection • Automatic timing method selection and timing control • Best Signal Analysis • Deflation Timing Management	Autopilot mode Includes: • Automatic trigger selection • Automatic ECG/ Arterial Pressure (AP) source selection • Automatic timing method selection and timing control • Best Signal Analysis • Deflation Timing Management	AC3 and AutoCAT2 series IABP systems have the same Autopilot mode functionality.
	Operator mode includes: • 7 modes for trigger selection	Operator mode includes: • 7 modes for trigger	AC3 and AutoCAT2 series IABP

Attribute	AutoCAT2 Series IABP (Predicate Device)	AC3 Series IABP system (Subject Device)	Comparison
	• ECG Source: 2 selections and 1 key press to change leads • ECG gain: Automatic, Manual and User adjustable • AP Source: 3 selections • AP Scaling: Automatic, Manual and User selectable • Timing can be selected using Soft keys and the selected timing setting is displayed on the screen.	selection • ECG Source: 2 selections and 1 key press to change leads • ECG gain: Automatic, Manual and User adjustable • AP Source: 3 selections • AP Scaling: Automatic, Manual and User selectable • Touchscreen has the timing controls under the Timing Key. A reminder message is shown if the user leaves the timing screen in 1:2 or lower assist.	systems have the same Operator mode functionality.
FiberOptix® Technology	AutoCAT2 WAVE® only: Allows Arterial Pressure (AP) to be measured by Fiber Optic method while using Arrow FiberOptix® IAB catheter.	AC3 Optimus™ only: Allows Arterial Pressure (AP) to be measured by Fiber Optic method while using Arrow FiberOptix® IAB catheter. The AC3 Series IABP system has an updated position for the FOS connection.	New position for the FOS connection will facilitate connection

5.9 Conclusion Regarding Substantial Equivalence

The AC3 Series IABP System has the same indications for use and incorporates the same fundamental technology as the legally marketed predicate devices. Performance test results and verification activities demonstrate that the proposed device meets its intended use. It is for these reasons that the proposed device can be found substantially equivalent to the predicate device.