November 12, 2019

Arrow International, Teleflex
Deb Fleetham
Manager, Regulatory Affairs
16 Elizabeth Drive
Chelmsford, Massachusetts 01824

Re: K192238
Trade/Device Name: AC3 Series Intra-Aortic Balloon Pump (IABP)
Regulation Number: 21 CFR 870.3535
Regulation Name: Intra-Aortic Balloon and Control System
Regulatory Class: Class II
Product Code: DSP
Dated: October 11, 2019
Received: October 15, 2019

Dear Deb Fleetham:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Fernando Aguel
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

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)*

K192238

Device Name

AC3 Series Intra-Aortic Balloon Pump (IABP)

Indications for Use *(Describe)*

The AC3 Intra-Aortic Balloon Pump is clinically indicated for use for the following conditions:
- Acute Coronary Syndrome
- Cardiac and Non-Cardiac Surgery
- 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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2 510(k) Summary

[As required by 21 CFR 807.92]

Date Prepared: November 7, 2019

510(k) Number: K192238

Submitter's Name / Contact Person

Manufacturer
Arrow International, Inc.
A Subsidiary of Teleflex
16 Elizabeth Drive
Chelmsford, MA 01824 USA
Establishment Registration # 3010532612

Contact Person
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Manager, Regulatory Affairs
Cardiac-Interventional BU
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General Information

Trade Name	AC3™ SERIES IAB Pump
Common / Usual Name	IAB Pump
Product Code	DSP
Classification Name	21 CFR 870.3535 – Intra-Aortic Balloon Pump, System
Predicate Device	K162820, AC3™ IAB Pump – cleared March 31, 2017

Device 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 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 catheter 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 catheter 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, and
- The pneumatic drive module which is incorporated into the body of the device

The AC3™ Series IABP is designed to be used with 30, 35, 40 and 50cc Intra-aortic balloons with the appropriate connectors.

The AC3™ Series IABP 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.

Indications for Use

The AC3™ Intra-Aortic Balloon Pump is clinically indicated for use for the following conditions:

- Acute Coronary Syndrome
- Cardiac and Non-Cardiac Surgery
- Complications of Heart Failure

Verification and Validation Testing

The software changes were developed in accordance with IEC 62304, Medical Device Software – Software Lifecycle Processes and in accordance with FDA Guidance "General Principles of Software Validation: Final Guidance for Industry and FDA Staff." Software Verification testing has been completed to demonstrate that the software requirements have been met. All testing met the expected results. System verification and validation testing was also conducted, and all results met the required specifications.

Technological Comparison to Predicate

The AC3™ IABP system with Ver. 3.11 software is similar in design and identical in Indications for Use to the predicate, AC3™ IABP system (V3.7). The AC3 IABP system with Ver. 3.11 software was aligned with the AutoCAT2 IABP system (predicate to AC3) for the Helium Loss 2 alarm. The differences between the subject AC3 system and the predicate IABP systems were evaluated to provide evidence that the AC3 IABP System is substantially equivalent to the predicate systems. The IABP systems were verified through software validation and system verification testing. The results of the testing met the acceptance criteria and performed similar to the predicate device (AutoCAT2 and AC3 Ver.3.7). The testing demonstrates that the catheter is substantially equivalent to the predicate device.

Table: Substantial Equivalence Comparison

Characteristic	Subject Device	Predicate Device
	AC3™ IABP System with SW V3.11	***AC3™ IABP System with SW V3.07 (K162820)***
Device Classification	Class II	Same
Regulation	21 CFR 870.3535	Same
Product Code	DSP – Intra-aortic balloon and control system	Same

Table: Substantial Equivalence Comparison		
Characteristic	**Subject Device**	**Predicate Device**
	AC3™ IABP System with SW V3.11	***AC3™ IABP System with SW V3.07 (K162820)***
Indications for Use	The AC3™ Intra-Aortic Balloon Pump is clinically indicated for use for the following conditions: • Acute Coronary Syndrome • Cardiac and Non-Cardiac • Surgery Complications of Heart Failure **There are no changes to the Indications for Use**	Same
Intended Use	The AC3™ Series IABP system is intended to provide counterpulsation 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.	Same
Compatible Disposable Balloon Catheters	30, 35, 40, and 50cc Intra-aortic balloon catheters	Same
Display	13.3" High-Resolution touchscreen display including 6 hard keys for frequently used or safety functions.	Same
	Hard keys and text are both backlit (LED) and color coded for visibility in the dark	
	AC3™ IABP Display head has a color-coded corner switch that illuminates when an alarm is active.	
Operational Modes	Two Operational Modes: Autopilot and Operator mode	Same
	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	

Table: Substantial Equivalence Comparison		
Characteristic	**Subject Device**	**Predicate Device**
	AC3™ IABP System with SW V3.11	***AC3™ IABP System with SW V3.07 (K162820)***
	Operator mode includes: • Seven modes for trigger selection • ECG Source: 2 Selection 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	
FiberOptix® Technology	Allows Arterial Pressure (AP) to be measured by FiberOptic method while using Arrow FiberOptix IAB catheters. The AC3™ Series IABP system has an updated position for the FOS connection	Same
Sterility	Non-Sterile	Same

Substantial Equivalence Conclusion

The AC3™ IABP with V3.11 software is substantially equivalent to the specified predicate device based on comparisons of the device functionality, principle of operation, technological characteristics, and indications for use. The change to the software and results of subsequent software verification and validations tests do not raise new or different questions of safety or effectiveness; therefore, the AC3™ IABP with V3.11 software is substantially equivalent to the predicate device.