August 30, 2023

Arrow International, LLC
Subsidiary of Teleflex, Inc.
Sheila Payzant
Senior Regulatory Affairs Specialist
3015 Carrington Mill Blvd
Morrisville, North Carolina 27560

Re: K232343
Trade/Device Name: AC3™ Series IABP
Regulation Number: 21 CFR 870.3535
Regulation Name: Intra-Aortic Balloon And Control System
Regulatory Class: Class II
Product Code: DSP
Dated: August 2, 2023
Received: August 4, 2023

Dear Sheila Payzant:

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,

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

Enclosure

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.

Submission Number *(if known)*

K232343

Device Name

AC3™ Series IABP

Indications for Use *(Describe)*

The AC3™ Intra-Aortic Balloon Pump is clinically indicated for use for the following conditions:
1. Acute Coronary Syndrome
2. Cardiac and Non-Cardiac Surgery
3. 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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510(k) Summary
[As required by 21 CFR 807.92]
Date Prepared: August 30, 2023
510(k) Number: K232343

Submitter's Name/Contact Person
Manufacturer
Arrow International, LLC
Subsidiary of Teleflex, Inc.
3015 Carrington Mill Boulevard
Morrisville, NC 27560
Establishment Registration #3010532612

Contact Person
Sheila Gretsch Payzant, J.D.,M.S.
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General Information

Trade Name	AC3™ Series IABP
Common Name	Intra-Aortic Balloon and Control System
Product Code	DSP
Classification	Class II
Regulation	21 C.F.R. §870.3535
Panel	Cardiovascular
Predicate Device	K201112 - AC3™ Series IAB Pump (cleared 27 May 2020)

Device Description

The AC3™ Series Intra-Aortic Balloon Pump (IABP) system is a professional use device that provides counterpulsation therapy to adult patients with impaired Left Ventricular (LV) Function. The AC3 Series IABP system consists of two (2) components: (1) the pump control/display module which incorporates a display, touch screen, and keypad for system operation and (2) the pneumatic drive module with attached wheels. It provides hemodynamic support of blood pressure and reduced cardiac work through volume displacement principles.

The IABP is attached to an intra-aortic balloon (IAB) 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.

Intended Use/Indications for Use

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

1. Acute Coronary Syndrome
2. Cardiac and Non-Cardiac Surgery
3. Complications of Heart Failure

Technological Characteristics Comparison

The subject device incorporates an updated software revision consisting of corrections to software anomalies, an enhancement permitting the disabling capability of the transfer of data via universal serial bus (USB), and other minor modifications for reliability and usability. The subject device also incorporates an alternate SD Card and battery .No changes introduced new risks to the user or the patient.

Conclusion

Compared with the predicate device, the AC3™ Series IABP has identical indications for use, fundamental technologies, principles of operation and performance. Substantial equivalence was demonstrated through software verification and validation testing. The results of these tests raised no new questions of safety or effectiveness and demonstrated that the subject AC3™ IABP is substantially equivalent to the predicate device.