March 26, 2025

Arrow International LLC
Apurva Gokhale
Pr. Regulatory Product Specialist
(Subsidiary of Teleflex Incorporated)
3015 Carrington Mill Boulevard
Morrisville, North Carolina 27560

Re: K250542
Trade/Device Name: AC3™ Range™ 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
Dated: February 24, 2025
Received: February 24, 2025

Dear Apurva Gokhale:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

TBD

Device Name

AC3™ Range™ Intra-Aortic Balloon Pump

Indications for Use *(Describe)*

The AC3™ Range™ 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.

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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510(k) Summary
[As required by 21 CFR 807.92]
Date Prepared: February 21, 2025
510(k) Number: K250542

Submitter's Name/Contact Person

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

Contact Person
Apurva N. Gokhale
Principal Regulatory Affairs Specialist
InterventionalPMRA@teleflex.com
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General Information

Trade Name	AC3™ Range™ Intra-Aortic Balloon Pump (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	K232343 - AC3™ Series IAB Pump (cleared 30 August 2023)

Device Description

The AC3 Range IABP system is a professional use device that 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 AC3 Range 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 for easy transport.

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 pump display incorporates a high-definition touchscreen with color coded icons and a keypad for system operation. The AC3 Range IABP uses software to select and maintain precise IAB catheter inflation and deflation timing and triggering based on real time physiological data from the patient. The system offers two modes of operation, (1) the AutoPilot mode, where most functions are automatically selected and controlled by IABP and (2) the Operator mode where the user has control over most settings and selections.

Intended Use/Indications for Use

The AC3™ Range™ Intra-Aortic Balloon Pump (IABP 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 AC3 Range IABP is a compact version of the AC3 Optimus IABP that has a low profile for improved transportability within air and ground transport modes (helicopter, plane, ambulance).

Substantial Equivalence and Summary of Studies

The technological differences between the subject and predicate device have been evaluated through Mechanical and General Safey Testing to provide evidence of substantial equivalence for the AC3 Range IABP.

Conclusion

The AC3 Range IABP has identical indications for use, fundamental technologies, principles of operation and performance compared to the predicate device. Substantial equivalence was demonstrated through Mechanical and General Safey Testing. The results of these tests raised no new questions of safety or effectiveness and demonstrated that the subject AC3 Range IABP is substantially equivalent to the predicate device.