May 27, 2020

Arrow International Inc.
Shajunath Nirupama
Senior Regulatory Affairs Specialist
16 Elizabeth Drive
Chelmsford, Massachusetts 01824

Re: K201112
Trade/Device Name: AC3 IABP, AC3 Optimus IABP, AutoCAT2 Wave IABP, AutoCAT2 IABP
Regulation Number: 21 CFR 870.3535
Regulation Name: Intra-Aortic Balloon And Control System
Regulatory Class: Class II
Product Code: DSP
Dated: April 24, 2020
Received: April 27, 2020

Dear Shajunath Nirupama:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K201112

Device Name
AutoCAT®2 Intra-Aortic Balloon Pump (IABP) and AC3™ Series Intra-Aortic Balloon Pump (IABP)

Indications for Use *(Describe)*
The AutoCAT®2 Intra-Aortic Balloon Pump (IABP) and AC3™ Series Intra-Aortic Balloon Pump (IABP) are 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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2 510(K) SUMMARY

[As required by 21 CFR 807.92]

Date Prepared: April 24, 2020

510(k) Number: K201112

Submitter's Name / Contact Person

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

Contact Person
Shajunath Nirupama
Sr. Regulatory Affairs Specialist
Shajunath.Nirupama@teleflex.com
usmin-vsireg@teleflex.com
Phone: 978-250-5100 ext. 725187

General Information

General Predicate Device Information		
Trade Name	AutoCAT2® Intra-Aortic Balloon Pump AC3 ™Series Intra-Aortic Balloon Pump	
Common Name	Intra-Aortic Balloon Pump	
510(k) Number	AutoCAT2 ® IABP K060309	AC3™Series IABP K192238
Reference 510(k) Number	K002256	K162820
510(k) Holder	Arrow International, Inc.	
Classification	II	
Regulatory Description	21 CFR 870.3535, Intra-aortic balloon and control system	
Product Code	DSP	
Panel	Cardiovascular	

Device Description

The AutoCAT Series Intra-Aortic Balloon Pump (IABP) System

The AutoCAT Series IABP System, including the AutoCAT®2 and AC3™ Series IABP's, provide counter-pulsation therapy to adult patients with impaired left ventricular (LV) function. They provide 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.

The AutoCAT Series IABP Systems 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 AutoCAT Series IABP are designed to be used with 30, 40 and 50cc IAB catheters with the appropriate connectors. The primary difference between the AutoCAT®2 IABP and AC3™ series IABP is the user interface, where the display is a touchscreen.

Indication for Use

The AutoCAT®2 Intra-Aortic Balloon Pump (IABP) and AC3™ Series Intra-Aortic Balloon Pump (IABP) are 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 AutoCAT Series IABP system, including AutoCAT®2 IABP and AC3™ Series IABP, are similar in design and identical in Indications for Use to the predicate IABP system. The motor connector on the MForce motor driver to IABP stepper motor, used in both the AutoCAT®2 and AC3™ Series, are being modified to increase the robustness of the IAB pump system.

The differences between the subject AutoCAT®2 and AC3™ systems and the predicate IABP systems were evaluated to provide evidence that the modification is substantially equivalent to the predicate systems.

The proposed modification to the IABP systems were verified through design verification testing as outlined on the following page.

- System Level Verification Testing
- Manufacturing Process Verification Test
- Performance / Durability Verification Testing

The results of the verification tests met the specified acceptance criteria and performed similar to the predicate device. The testing demonstrates that the subject devices are substantially equivalent to the predicate devices.

Substantial Equivalence Conclusion

The subject AutoCAT®2 and AC3™ series Intra-Aortic Balloon Pump (IABP) are substantially equivalent to the specified predicate devices (cleared under K060309 and K192238, respectively) based on a comparison of the device functionality, technological characteristics, and indications for use.

The device modifications and results of design verification tests do not raise new or different questions of safety or effectiveness; therefore, the subject devices are substantially equivalent to the predicate devices.