June 28, 2019

Arrow International, Inc.
Niyati Boghani
Regulatory Affairs Specialist
16 Elizabeth Drive
Chelmsford, Massachusetts 01824

Re: K190101
Trade/Device Name: UltraFlex IAB
Regulation Number: 21 CFR 870.3535
Regulation Name: Intra-Aortic Balloon And Control System
Regulatory Class: Class II
Product Code: DSP
Dated: April 30, 2019
Received: May 2, 2019

Dear Niyati Boghani:

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)*

K190101

Device Name
UltraFlex™ IAB

Indications for Use *(Describe)*

UltraFlex™ IAB with Intra-Aortic Balloon Pump as a control system is indicated for use in any of 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.

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# 2. 510(k) Summary

[As required by 21 CFR 807.92]

Date Prepared: June 18, 2019

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|---|---|
| **Submitter** | Arrow International, Inc. (Subsidiary of Teleflex, Inc.)<br>16 Elizabeth Drive<br>Chelmsford, MA 01824<br>Establishment Registration: 3010532612<br><br>Arrow International, Inc. (Subsidiary of Teleflex, Inc.)<br>Reading, PA 19605:<br>Owner/ Operator: 2518433 |
| **Company Contact** | Deb Fleetham<br>Manager, Regulatory Affairs<br>Arrow International, Inc.<br>16 Elizabeth Drive<br>Chelmsford, MA 01824<br>deb.fleetham@teleflex.com<br>Phone: (612) 403-3806 |
| **Trade Name** | Proprietary Name: UltraFlex™ IAB<br>Common Name: Intra-Aortic Balloon Catheter (IAB)<br>Product Code: DSP<br>Classification Name: Intra-aortic balloon and control system (21 CFR 870.3535). Regulatory Class II |
| **Legally Marketed Predicate Devices** | • K993966 Arrow 8Fr. NarrowFlex® Universal Intra-Aortic Balloon Catheter (Arrow International, Inc.- Cleared February 18, 2000) |
| **Reference Devices** | • K010330 Arrow RediGuard® 9 Fr. 50cc Universal Intra-Aortic Balloon Catheter (Arrow International, Inc.- Cleared March 2, 2001)<br>• K000729 Arrow Ultra 8® 8 Fr. 30cc and 40cc Universal Intra-Aortic Balloon Catheter (Arrow International, Inc.- Cleared May 19, 2000) |
| **Device Description** | The UltraFlex IAB consists of an inflatable balloon, which is placed in the aorta to improve cardiovascular functioning. A computerized control system, also known as Intra-Aortic Balloon Pump (IABP) regulates the inflation and deflation of the balloon.<br><br>The UltraFlex IAB catheter consists of an inner lumen, an outer lumen, and an inflatable balloon. The outer lumen is comprised of an inflatable balloon connected to the distal tip of the catheter shaft and to the IAB catheter tip |

outer surface. The inner lumen is comprised of a luer adapter connected to the proximal end of the inner lumen and to the IAB catheter tip inner surface.

**Indications of Use**

The UltraFlex IAB with the intra-aortic balloon pump as a control system is indicated for use in any of the following conditions:
1. Acute Coronary Syndrome.
2. Cardiac and Non-Cardiac Surgery
3. Complications of Heart Failure

**Technological Characteristics Comparison**

The subject UltraFlex IAB is similar in design and identical in indications for use to the predicate device, Arrow 8Fr. NarrowFlex® Universal Intra-Aortic Balloon Catheter. Compared to the predicate device, UltraFlex IAB has a modified central lumen, increased balloon size/volume, and the size of the supplied insertion sheath and dilator was increased to accommodate the larger balloon.

The technological differences between the subject and the predicate devices have been evaluated through bench tests to provide evidence that the UltraFlex IAB is substantially equivalent to the predicate device. The device design has been verified through the following tests:

- Catheter Insertion Test
- Aneurysm Test
- Durability Test
- Catheter Tip to Balloon Bond Tensile per ISO 10555-1
- Outer Lumen to Balloon Bond Tensile per ISO 10555-1
- Sheath and Dilator Surface Visual Inspection per ISO 11070
- Sheath and Dilator Tensile Testing per ISO 11070
- Balloon Volume Test
- Catheter Rate Limit Test
- Kink Resistance
- Sheath and Dilator Dimensional Analysis

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

**Substantial Equivalence Conclusion**

The subject UltraFlex IAB Catheter is substantially equivalent to the specified predicate device based on 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. The subject device is substantially equivalent to the predicate device.