April 9, 2020

Arrow International Inc.
Apurva Gokhale
Senior Regulatory Affairs Specialist
16 Elizabeth Drive
Chelmsford, Massachusetts 01824

Re: K200634
Trade/Device Name: FiberOptix Intra-Aortic Balloon Catheter Kit
Regulation Number: 21 CFR 870.3535
Regulation Name: Intra-Aortic Balloon And Control System
Regulatory Class: Class II
Product Code: DSP
Dated: March 6, 2020
Received: March 10, 2020

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 (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,

for 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)*
K200634

Device Name
FiberOptix® Intra-Aortic Balloon Catheter Kit

Indications for Use *(Describe)*
The FIBEROPTIX IAB Catheter with the Intra-Aortic Balloon Pump as a control system is clinically 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.

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2. 510(k) Summary

[As required by 21 CFR 807.92]

Date Prepared: 6 March 2020

Submitter

Arrow International, Inc. (Subsidiary of Teleflex, Inc.)
16 Elizabeth Drive
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Establishment Registration: 3010532612

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Company Contact

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Regulatory Information

Proprietary Name:	FiberOptix® Intra-Aortic Balloon Catheter Kit
Common Name:	System, Balloon, Intra-Aortic and Control System
Product Code:	DSP
Regulation #	870.3535
Description:	Intra-aortic balloon & control system
Regulatory Class:	Class II

Legally Marketed Predicate Device

- K190117 Arrow FiberOptix IAB (Arrow International, Inc. – Cleared June 13, 2019)- Primary Predicate

Device Description

The FiberOptix® Intra-Aortic Balloon (IAB) Catheter 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) is utilized to regulate the inflation and deflation of the balloon.

The FiberOptix® 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.

The FiberOptix® IAB Catheter has a fiber optic pressure sensor which acts as a pressure transducer embedded in the catheter tip.

Intended Use

The FiberOptix® IAB Catheter is utilized for intra-aortic balloon counterpulsation therapy in the aorta, whereby balloon inflation, during diastole and deflation during systole increases blood supply to the heart muscle and decreases work of the left ventricle.

Indications for Use

The FiberOptix® IAB Catheter with the Intra-Aortic Balloon Pump as a control system is clinically 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 FiberOptix® IAB catheter is similar in design and identical in indications for use to the predicate devices, Arrow Intra-Aortic Balloon Fiber Optic Sensor/ Fiber Optic Measurement System and Arrow FiberOptix IAB Catheter. Compared to the predicate devices, the subject FiberOptix® IAB has a modified configuration of the fiber optic sensor along the distal length of the IAB catheter to improve its robustness.

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

- Insertion, Durability Test & (FOS) Static Pressure Test
- Simulated Misuse Test & (FOS) Static Pressure Test

The results of the verification test met the specified acceptance criteria and performed similar to the predicate device. The testing demonstrates that the subject FiberOptix® IAB catheter is substantially equivalent to the predicate device.

Substantial Equivalence Conclusion

The subject FiberOptix® IAB Catheter is substantially equivalent to the specified predicate device, FiberOptix® IAB Catheter (K021462 and K190117) based on a comparison of the device functionality, materials, 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 device is substantially equivalent to the predicate device.