DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 13, 2016

Arrow International, Inc.
Ms. Christine Ford
Sr. Regulatory Affairs Manager
2400 Bernville Rd
Reading, PA 19605

Re: K160018
Trade/Device Name: Arrow Quickflash Arterial Catheterization Device
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX, DQY
Dated: May 11, 2016
Received: May 16, 2016

Dear Ms. Ford:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kenneth J. Cavanaugh -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160018

Device Name
Arrow Quickflash Arterial Catheterization Device

Indications for Use *(Describe)*
The Arrow Arterial Catheterization Device permits access to the peripheral arterial circulation or to other small vessels.

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
FOR
THE ARROW QUICKFLASH ARTERIAL CATHETERIZATION DEVICE

1. Submitter Information

Name:	Arrow International, Inc. (subsidiary of Teleflex Inc.)
Address:	2400 Bernville Road Reading, PA 19605-9607
Telephone Number:	(610) 378-0131
Contact Person:	Christine Ford Sr. Regulatory Affairs Manager
Telephone Number:	(610) 378-0131
Fax Number:	(610) 374-5360
Email:	christine.ford@teleflex.com
Date Prepared:	12-MAY-2016

2. Device Name

Device Trade Name:	Arrow® Quickflash Arterial Catheterization Device
Common Name:	Peripheral Intravascular Catheter
Classification Name:	Catheter guide wire, (Class II, DQX, 21 CFR 870.1330) Percutaneous catheter, (Class II, DQY, 21 CFR 870.1250)

3. Predicate Devices

- K810675: Arrow® Radial Artery Catheterization Set

4. Device Description

The primary purpose of this Traditional 510(k) submission is for labeling modification to the Arrow Radial Artery Catheterization Set (K810675). Specifically, clarifications to the contraindications and warnings sections of the device labeling have been introduced as well as modifications to the recommended procedural technique to facilitate efficiencies in verbiage and add clarity. The subject device, the Arrow® Quickflash Arterial Catheterization Device, which is a sterile, single use arterial catheterization device, is designed to permit access to the peripheral arterial circulation or to other small vessels. The Arrow® Quickflash Arterial Catheterization Device is an all-in-one design consisting of a translucent polyurethane, radiopaque single lumen arterial catheter-over-needle device that includes a clear chamber as part of the needle hub which allows visualization of blood flashback. The needle has openings to enhance flashback visibility and the hub is connected proximally to a slotted housing that contains the integral spring wire guide. A handle projects through the slotted housing to permit the advancement of the spring wire guide through the introducer needle into the vessel. This design allows for quick and simple catheter insertion since all of the devices required for insertion are provided together.

The Arrow Quickflash Arterial Catheterization Device is available with and without integrated molded suture wings in 20 gauge configurations with usable lengths of 3.81 cm (1 ½").

5. Intended Use

The catheter is intended for short-term use (less than 30 days) to permit access to peripheral vessels.

6. Indications for Use

The indications for use for the subject device are identical to the predicate and are listed below:

The Arrow Arterial Catheterization Device permits access to the peripheral arterial circulation or to other small vessels.

7. Technological Characteristics

Information related to cumulative design modifications which have been implemented in the subject device are included and are summarized below.

Design Feature	Predicate device: Arrow® Radial Artery Catheterization Set (K810675)	Subject device: Arrow® Quickflash Arterial Catheterization Device
Catheter body OD	18, 20 Ga	20 Ga
Catheter length	1 3/4 inches (4.45cm)	1 ½ inches (3.81cm)
Catheter body material	Teflon	Polyurethane with20% Barium Sulfate
Blood Flashback Visualization	Clear introducer needle proximal hub.	Transparent Quickflash blood flashback visualization chamber.
Integrated Guide wire	Yes	Yes
Guide wire material/size	Stainless Steel 0.018", Straight, soft tip	Stainless Steel 0.018", Straight, soft tip
Sterilization Method	EO	EO

8. Nonclinical Testing

Bench test results related to design verification associated with the current design of the Arrow Quickflash Arterial Catheterization Device are included in support of the substantial equivalence of the subject device. The following testing has been completed for the subject device:

- Biocompatibility in accordance with ISO 10993-1, 10999-3, 10993-4, 10993-5, 10993-10, and 10993-11
- Requirements from ISO 10555 and ISO 11070 including:
  - Surface
  - Corrosion Resistance
  - Freedom from leakage (Air and Liquid)
  - Tensile Testing
- Luer testing in accordance with ISO 594-1 & ISO 594-2
- Simulated Use testing
- Penetration/Insertion force
- Catheter Kink resistance in accordance with BS EN 13868
- Dimensional Verification
- Needle Flexing Durability
- Spring Wire Guide Flexing Durability
- Catheter Resistance to Collapse

9. Conclusions

The labeling modifications proposed to the subject device do not alter the intended use, indications for use, fundamental technology, or fundamental method of operation of the subject device. Summary verification results support the substantial equivalence of the subject Arrow Quickflash Arterial Catheterization Device, to the legally marketed predicate device, Arrow® Radial Artery Catheterization Set (K810675).