DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 23, 2017

Arrow International, Inc.
Ms. Fallon Young
Associate Regulatory Affairs Specialist
2400 Bernville Road
Reading, PA 19605

Re: K171146
Trade/Device Name: Arrow Seldinger Arterial Catheterization Device
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: May 25, 2017
Received: May 30, 2017

Dear Ms. Young:

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,

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)*
K171146

Device Name
Arrow Seldinger Arterial Catheterization Device

Indications for Use *(Describe)*
The Arrow Seldinger Arterial Catheterization Devices permit 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

(as required by the Safe Medical Devices Act of 1990 and in accordance with 21 CFR §807.92(a))

FOR

ARROW SELDINGER 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 Peron:	Fallon Young Associate Regulatory Affairs Specialist
Telephone Number:	(610) 984-7188
Fax Number:	(610) 374-5360
Email:	fallon.young@teleflex.com
Date Prepared:	April 18, 2017

2. Device Name

Device Trade Name:	Arrow Seldinger Arterial Catheterization Device
Common Name:	Percutaneous Arterial Catheter
Classification Name:	Catheter, percutaneous

(Class II, DQY, 21 CFR 870.1250)

3. Predicate Devices

- K093050: Arrow Seldinger Arterial Catheterization Devices

4. Device Description

The subject Arrow Seldinger Arterial Catheterization Devices consist of either an introducer needle or catheter-over-needle assembly, spring wire guide, and a catheter assembly that incorporates an extension tubing segment with a slide clamp and a luer hub with dust cap. These components are used together for catheter insertion using the "Seldinger" catheter-over-guide-wire insertion technique.

The predicate Arrow Seldinger Arterial Catheterization Devices are currently available in 18 ga. and 20 ga. configurations with usable lengths of 5cm to 23cm. The subject device will extend the device configurations to include 22 ga. and 24 ga. catheters with usable lengths of 2.5 cm to 23 cm and will add guide wire sizes that are compatible with the

additional catheter sizes. The subject device also introduces a new catheter and juncture hub material in place of the predicate materials for all gauge sizes.

The overall device description of the subject and predicate Arrow Seldinger Arterial Catheterization Devices is the same.

5. Intended Use

The Arrow Seldinger Arterial Catheterization Devices permit access to the peripheral arterial circulation or to other small vessels. These catheters may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness of procedure.

6. Indications for Use

The Arrow Seldinger Arterial Catheterization Devices permit access to the peripheral arterial circulation or to other small vessels.

7. Technological Characteristics

The subject Arrow Seldinger Arterial Catheterization Devices employs the same fundamental scientific technology as the predicate Arrow Seldinger Arterial Catheterization Devices.

The changes made to the subject device Arrow Seldinger Arterial Catheterization Devices are the product line extension and catheter extrusion and juncture hub material changes. Arrow International's legally marketed predicate device, the Arrow Seldinger Arterial Catheterization Device (K093050), was cleared with the configurations of 18 and 20 gauge catheters with usable lengths of 5-23 centimeters. The subject device configurations will extend the product line to include 22 and 24 gauge catheters with usable lengths of 2.5-23 centimeters. The product line expansion modifications add compatible spring wire guide sizes and a commercially available catheter-over-needle assembly component for use with the 24 ga. device. The subject device modifications also include a material change to the catheter extrusion and a material change to the juncture hub.

Testing on the modifications to the subject device verified that the changes presented no different questions of safety or efficacy.

Below is a comparison table to highlight the similarities and differences in the subject and predicate Arrow Seldinger Arterial Catheterization Devices.

DEVICE COMPARISON TABLE		
	Predicate Device: Arrow Seldinger Arterial Catheterization Devices K093050	**Subject Device: Arrow Seldinger Arterial Catheterization Devices**
Indications for Use	The Arrow Seldinger Arterial Catheterization Devices permit access to the peripheral arterial circulation or to other small vessels	**SAME:** The Arrow Seldinger Arterial Catheterization Devices permit access to the peripheral arterial circulation or to other small vessels
Device Design Feature		
Catheter Gauge Sizes	18 ga, 20 ga	18 ga, 20 ga, 22 ga, 24 ga
Catheter Usable Length	5cm – 23cm (2"– 9 ¼")	2.5cm – 23cm (0.98"– 9 ¼")
Introducer needle size	18 ga.: 18 ga X 5cm-7cm (2"- 2 ¾") 20 ga.: 20 ga. X 4 cm-7cm (1 ½ "- 2 ¾")	**SAME:** 18 ga.: 18 ga X 5cm-7cm (2"- 2 ¾") **SAME:** 20 ga.: 20 ga. X 4cm-7cm (1 ½"- 2 ¾") **NEW:** 22 ga.: 22 ga. X 4cm (1 ½")
Catheter-Over-Needle Size (only 24 ga.)	N/A	Needle: 26 ga. X 2cm (3/4") Catheter: 24 ga. X 2cm (3/4")
Spring Wire Guide Size	18 ga.: 0.64mm diameter X 33.5cm-60cm (13"-23") 20 ga.: 0.533mm diameter X 35cm-50cm (13 ¾"-20")	**SAME:** 18 ga.: 0.64mm diameter X 33.5cm-60cm (13"-23") **SAME:** 20 ga.: 0.533mm diameter X 35cm-50cm (13 ¾"-20") **SAME:** 22 ga.: 0.533mm diameter X 35cm (13 ¾") **NEW:** 24 ga.: 0.46mm diameter X 25cm (9 ¾")
Spring Wire Guide Tip	Straight and J-tip	**SAME:** Straight and J-tip
Spring Wire Guide Depth Markings	Yes, etched on straight spring wire guides. Not on J-tip spring wire guides	**SAME:** Yes, etched on straight spring wire guides. Not on J-tip spring wire guides
Introducer Method	Introducer needle	Introducer needle and introducer catheter-over-needle
Sterilization		
Sterilization Method	EO	**SAME:** EO
Shelf life and packaging		
Shelf life	5 years	2 years
Packaging	PET/LDPE film mated with Tyvek	**SAME:** PET/LDPE film mated with Tyvek

Apart from the additional catheter sizes with associated component additions and the material changes to the extrusion and juncture hub, no other changes have been made to the subject Arrow Seldinger Arterial Catheterization Devices in comparison to Arrow International's legally marketed predicate, the Arrow Seldinger Arterial Catheterization

Devices (K093050). The indications for use and fundamental scientific technology of the subject and predicate devices are the same.

8. Nonclinical Testing

Bench testing performed on the subject Arrow Seldinger Arterial Catheterization Devices supports substantial equivalence to the predicate device. The following testing has been conducted as a result of the device modifications:

- Biocompatibility in accordance with ISO 10993-1
- Applicable requirements from ISO 10555-1
    - Surface: Extraneous Matter and External Surface
    - Resistance to Kink
    - Peak Tensile Force
    - Air Leakage
    - Liquid Leakage
- Applicable requirements from ISO 11070 including:
    - Surface: Extraneous Matter and Defects
    - Guide wire Fracture
    - Guide wire Flexure
    - Guide wire Tensile
    - Needle Point
    - Peak Tensile Force
    - Strength of Union of Needle Tube and Needle Hub
- Guide wire Stiffness
- Guide wire Interface
- Simulated Blood Withdrawal
- Pressure Monitoring
- Penetration Force
- Radio Detectability

9. Conclusions

The predicate and subject Arrow Seldinger Arterial Catheterization Devices have the same indications for use, intended use, and fundamental scientific technology, and are manufactured using the same processes, conditions, and aids. The results of the risk assessment and resultant testing performed have demonstrated that the proposed device

modifications present no different questions of safety or effectiveness and therefore the subject device is considered substantially equivalent to the cited predicate devices.