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

Arrow International, Inc. (subsidiary of Teleflex Inc.)
% Fallon Young
Associate Regulatory Affairs Specialist
2400 Bernville Road
Reading, Pennsylvania 19605

February 24. 2017

Re: K163513
Trade/Device Name: Arrow Endurance Extended Dwell Peripheral Catheter System
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: Class II
Product Code: FOZ
Dated: January 26, 2017
Received: January 27, 2017

Dear Ms. Fallon 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,

Susan Runner DDS, MA

For Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental 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)*
K163513

Device Name

Arrow Endurance™ Extended Dwell Peripheral Catheter System

Indications for Use *(Describe)*

The ARROW Endurance catheter system permits access to the patient's peripheral vascular system for short-term use to sample blood, monitor blood pressure, or administer fluids. The catheter may be used for high pressure injection. The safety feature is intended to minimize the risk of sharps injuries.

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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K163513

510(K) SUMMARY

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

1. Submitter Information

Name:	Arrow International, Inc. (subsidiary of Teleflex Inc.)
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Email:	fallon.young@teleflex.com
Date Prepared:	February 23, 2017

2. Device Name

Device Trade Name:	Arrow® Endurance™ Extended Dwell Peripheral Catheter System
Common Name:	Peripheral Intravascular Catheter
Classification Name:	Catheter, intravascular, therapeutic

(Class II, FOZ, 21 CFR 880.5200)

3. Predicate Devices

- K152272: Arrow® Endurance™ Extended Dwell Peripheral Catheter System
- K151513: Arrow® Endurance™ Extended Dwell Peripheral Catheter System

4. Device Description

The Arrow® Endurance™ Extended Dwell Peripheral Catheter System is a sterile, single use peripheral intravascular device designed to permit access to the peripheral vascular system. The insertion device consists of a handle with an integral needle, a passively-activated needle protection mechanism, guide wire with slider advancer, catheter release tab, and single-lumen catheter. The catheter is advanced over the needle and threaded over a guide wire into a peripheral vessel. The catheter system consists of a catheter body, juncture hub, integrated extension tubing with Luer hub, vent plug to prevent blood leakage during insertion, and a clamp.

The catheter is intended for short-term use to permit delivery of infusion therapies, infusion of blood and blood products, pressure monitoring, high pressure injection at a maximum of 325 psi, and withdrawal of blood.

The Arrow Endurance Extended Dwell Peripheral Catheter System is available in single lumen, 18 ga. 20 ga. and 22 ga. configurations with usable lengths of 6 cm (2.36") and 8 cm (3.15").

The overall device description of the subject and predicate Arrow Endurance Extended Dwell Peripheral Catheter Systems are the same.

5. Intended Use

The Arrow Endurance Extended Dwell Peripheral Catheter System is intended for short- term use to permit delivery of infusion therapies, infusion of blood and blood products, pressure monitoring, high pressure injection and withdrawal of blood.

The subject Arrow Endurance Extended Dwell Peripheral Catheter System intended use statement is the same as the predicate Arrow Endurance Extended Dwell Peripheral Catheter System intended use statement.

6. Indications for Use

The ARROW Endurance catheter system permits access to the patient's peripheral vascular system for short-term use to sample blood, monitor blood pressure, or administer fluids. The catheter may be used for high pressure injection. The safety feature is intended to minimize the risk of sharps injuries.

7. Technological Characteristics

The Arrow Endurance Extended Dwell Peripheral Catheter System is substantially equivalent to the predicate Arrow Endurance Extended Dwell Peripheral Catheter System (K152272 & K151513) in terms of indications for use, intended use, and functional performance.

The only changes made to the subject device Arrow Endurance Extended Dwell Peripheral Catheter System are the guide wire design change and the catheter release colorant change. The modifications to the device's guide wire are shortening the flexible distal portion of the wire and the removal of the stainless steel coil/spring on the distal end of the guide wire. The overall length of the guide wire and the core nitinol wire material are the same as the predicate Endurance device. The modification to the device's catheter release is the addition of one (1) colorant. The base resin will remain the same. Testing on the subject guide wire and catheter release 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 Endurance Extended Dwell Peripheral Catheter Systems.

Predicate(s) and Subject Device Comparison

Design Feature	Predicate Device: Arrow Endurance Extended Dwell Peripheral Catheter System K151513	Predicate Device: Arrow Endurance Extended Dwell Peripheral Catheter System K152272	Subject Device: Arrow Endurance Extended Dwell Peripheral Catheter System
Catheter Body OD	20 Ga	18 Ga and 22 Ga	SAME: 18 Ga, 22 Ga, 20 Ga
Catheter Body ID	0.032" (20 Ga)	0.039 " (18 Ga) 0.027" (22 Ga)	SAME: 0.039 " (18 Ga) 0.027" (22 Ga) 0.032" (20 Ga)
Catheter Body Material	Polyurethane	Polyurethane	SAME: Polyurethane
Catheter Usable Length	6 cm (2.36") 8 cm (3.15")	6 cm (2.36") 8 cm (3.15")	SAME: 6 cm (2.36") 8 cm (3.15")
Cather Body Radiopacifier	20% Barium Sulfate	20% Barium Sulfate	SAME: 20% Barium Sulfate
Needle Safety Feature	Yes	Yes	SAME: Yes
Blood Safety Feature	Bloodless (seal and extension lines)	Bloodless (seal and extension lines)	SAME: Bloodless (seal and extension lines)
Pressure Injection Limits	325 psi	325 psi	SAME: 325 psi
Sterilization Method	EO	EO	SAME: EO
Flashback Visualization	Yes	Yes	SAME: Yes
Guide Wire Comparison			
Integrated Guide Wire	Yes	Yes	SAME: Yes
Guide Wire Coating	None	None	SAME: None
Guide Wire Overall Size	0.010"	0.010"	SAME: 0.010"
Effective Guide Wire Length	4 cm	4 cm	SAME: 4 cm
Atraumatic Tip	Yes	Yes	SAME: Yes
Guide Wire Material	Nitinol	Nitinol	SAME: Nitinol
Guide Wire Coil Material	Stainless Steel	Stainless Steel	N/A – No Coil
Catheter Release Material			
Base Material	Blue Polycarbonate	Blue Polycarbonate	SAME: Blue Polycarbonate

With exception of the changes to the guide wire and the catheter release, no other changes have been made to the subject Arrow Endurance Extended Dwell Peripheral Catheter System in comparison to Arrow International's legally marketed predicate devices, the Arrow Endurance Extended Dwell Peripheral Catheter System (K152272 & K151513).

8. Nonclinical Testing

Bench testing performed on the Arrow Endurance Extended Dwell Peripheral Catheter System supports substantial equivalence of the subject 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 11070 including:
    - Surface: Extraneous Matter and Defects
    - Surface: Lubricant
    - Guide wire Radio Detectability
    - Guide wire Fracture
    - Guide wire Flexure
    - Guide wire Tensile
- Guide wire Stiffness
- Simulated Use Testing

9. Conclusions

The predicate and subject Arrow Endurance Extended Dwell Peripheral Catheter System devices have the same indications for use, intended use, method of application and mechanism of release 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 guide wire design and catheter release colorant change present no different questions of safety or effectiveness and therefore the subject device is considered substantially equivalent to the cited predicate devices.