



Food and Drug Administration
10903 New Hampshire Avenue
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July 8, 2015

Arrow International
c/o Mr. Dave Yungvirt
Third Party Review Group, LLC
45 Rockefeller Plaza, Suite 2000
New York, NY 10111

Re: K151513

Trade/Device Name: Arrow[®] Endurance[™] Extended Dwell Peripheral Catheter System

Regulation Number: 21 CFR 880.5200

Regulation Name:

Regulatory Class: II

Product Code: FOZ

Dated: June 21, 2015

Received: June 23, 2015

Dear Mr. Yungvirt:

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" (21CFR 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,

 Tina
Kiang -S

for Erin I. Keith, M.S.

Director

Division of Anesthesiology, General Hospital,

Respiratory, Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K151513

Device Name: Arrow Endurance™ Extended Dwell Peripheral Catheter System

Indications for Use:

The ARROW Endurance catheter system permits access to the patient’s peripheral vascular system for short-term use (less than 30 days) 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.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) SUMMARY

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

FOR

THE ARROW ENDURANCE™ EXTENDED DWELL PERIPHERAL CATHETER SYSTEM (K151513)

1. Submitter Information

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Date Prepared: March 16, 2015

2. Device Name

Device Trade Name: Arrow® Endurance™ Extended Dwell Peripheral Catheter System
Common Name: Peripheral Intravascular Catheter
Classification Name: Catheter, intravascular, therapeutic, short-term less than 30 days (Class II, FOZ, 21 CFR 880.5200)

3. Predicate Devices

- K032843: Nexiva Closed IV Catheter System
- K021120: Radial Artery Catheterization Set with Integral Needle Protection

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 an ergonomically designed handle with an integral echogenic needle with 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. Throughout catheter insertion, blood is contained within the device to aid in prevention of blood exposure. The catheter system consists of a translucent radiopaque polyurethane catheter, a needle with openings to enhance flashback visibility, a seal in the catheter hub designed to reduce blood exposure, a stabilization platform with a strain relief nose designed to reduce kinking at the hub of the catheter, integrated extension tubing with Luer hub, vent plug to prevent blood from leaking out during insertion, and a clamp to eliminate blood exposure when the vent plug is removed and replaced with a mating Luer component such as an infusion set or Luer access device. The catheter is intended for short-term use (less than 30 days) 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, 20 gauge configurations with usable lengths of 6 cm (2.36”) and 8 cm (3.15”).

5. Intended Use

The Arrow Endurance™ Extended Dwell Peripheral Catheter System is intended for short-term use (less than 30 days) to permit delivery of infusion therapies, infusion of blood and blood products, pressure monitoring, high pressure injection and withdrawal of blood.

6. Indications for Use

The Arrow Endurance catheter system permits access to the patient’s peripheral vascular system for short-term use (less than 30 days) 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 Nexiva Closed IV Catheter System (K032843) and the predicate Arrow Radial Artery Catheterization Set with Integral Needle Protection (K021120) in terms of indications for use, intended use, general design, functional performance and materials of construction.

Design Feature	Subject device: Arrow Endurance™ Extended Dwell Peripheral Catheter System	Predicate device: Nexiva Closed IV Catheter System (K032843)	Predicate devices: Radial Artery Cath. Set with Integral Needle Protection (K021120)
Catheter body OD	20 Ga	18, 20, 22, 24 Ga	20 Ga
Catheter body ID	0.032” (20 Ga)	0.039”, 0.033” (20ga), 0.026”, 0.021”	0.0325”(20 Ga)
Catheter body material	Polyurethane	Polyurethane	Polyurethane
Catheter usable length	6 cm(2.36”) 8 cm(3.15”)	1.42cm(0.56”) 1.91cm(0.75”) 2.54cm(1.0”) 3.18cm(1.25”) 4.45cm(1.75”)	4.45 cm(1.75”)
Catheter body Radiopacifier	20% Barium Sulfate	Unknown	20% Barium Sulfate
Integrated Guide wire	Yes	No	Yes
Guide wire material/size	Stainless Steel and Nitinol/0.010”	N/A	Stainless Steel /0.018”
Needle safety feature	Yes	Yes	Yes
Blood safety feature	Bloodless (seal and extension line)	Bloodless (seal and extension line)	None
Pressure Injection Limits	325 psi	300 psi	N/A
Sterilization Method	EO	EO	EO
Flashback visualization	Yes	Yes	Yes

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 completed for the subject device:

- Biocompatibility in accordance with ISO 10993-1
- Requirements from ISO 10555 and ISO 11070 including:
 - Radio-Detectability
 - Surface
 - Corrosion Resistance
 - Freedom from leakage (Air and Liquid)
 - Flow rate
 - Pressure Injection
 - Tensile Testing
 - Blood Containment
- Luer testing in accordance with BS EN 20594-1(ISO 594-1) & BS EN 1707
- Simulated Use testing
- Penetration/Insertion force
- Sharps Safety Feature performance in accordance to CDRH Sharps Guidance and ISO 23908
- Catheter Kink resistance in accordance to BS EN 13868

9. Conclusions

The described intended use, results of verification testing performed, comparison of design and fundamental technology and comparison testing to the predicate devices demonstrated that the subject device, Arrow Endurance™ Extended Dwell Peripheral Catheter System, is substantially equivalent to the legally marketed predicate devices, Nexiva Closed IV Catheter System (K032843) and Radial Artery Catheterization Set with Integral Needle Protection (K021120). Any differences between the subject device and predicate devices do not raise new issues of safety and effectiveness.