December 20, 2024

Arrow International, LLC (A Subsidiary of Teleflex, Inc.)
Kim Pennington
Senior Regulatory Affairs Specialist
3015 Carrington Mill Blvd
Morrisville, North Carolina 27560

Re: K242281
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: November 22, 2024
Received: November 22, 2024

Dear Kim Pennington:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Porsche Bennett,
For David Wolloscheck, Ph.D.
Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices, and
Human Factors
OHT3: Office of Gastrorenal, ObGyn,
General Hospital, and Urology 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K242281

Device Name
Arrow™ Endurance™ Extended Dwell Peripheral Catheter System

Indications for Use *(Describe)*
The Arrow™ Endurance™ Extended Dwell Peripheral Catheter System permits access to the patient's peripheral vascular system for short-term venous use (less than 30 days) to sample blood, administer fluids, and perform high pressure contrast injections at a maximum of 325 psi.

The Arrow™ Endurance™ Extended Dwell Peripheral Catheter System permits access to the patient's peripheral vascular system for short-term use (less than 30 days) to facilitate arterial blood pressure measurement and blood sampling.

The safety feature is intended to minimize the risk of sharps injuries.

The Arrow™ Endurance™ Extended Dwell Peripheral Catheter may be used for any patient population with consideration given to adequacy of anatomy and appropriateness of the procedure.

The Arrow™ Endurance™ Extended Dwell Peripheral Catheter may be used in hospitals, clinics, and other advanced clinical facilities.

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.

510(k) SUMMARY- K242281

1. Submitter Information

Name:	Arrow International, LLC (a subsidiary of Teleflex Inc.)
Address:	3015 Carrington Mill Blvd Morrisville, NC 27560
Telephone Number:	(610) 451-3095
Contact Person:	Kim Pennington Sr. Regulatory Affairs Specialist
Email:	kim.pennington@teleflex.com
Date Prepared:	December 20, 2024

2. Device Name

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

3. Predicate Device

K163513: Arrow™ Endurance™ Extended Dwell Peripheral Catheter System
Common Name: Intravascular Catheter
Classification Name: Catheter, intravascular, therapeutic, short-term less than 30 days (Class II, FOZ, 21 CFR 880.5200)

4. Device Description

The subject device, 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 Endurance catheter is intended to permit access to the patient's peripheral vascular system for short-term venous use to sample blood, administer fluids and for high pressure contrast injections at a maximum of 325 psi. The Arrow™ Endurance™ Extended Dwell Peripheral Catheter System permits access to the patient's peripheral vascular system for short-term arterial use to monitor arterial blood pressure and blood sampling. The safety feature is intended to minimize the risk of sharps injuries.

The Arrow™ Endurance™ Extended Dwell Peripheral Catheter System is available in single lumen, 20 and 22 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 to access to the patient's peripheral vascular system for short-term venous or short-term arterial use.

6. Indications for Use

The Arrow™ Endurance™ Extended Dwell Peripheral Catheter System permits access to the patient's peripheral vascular system for short-term venous use (less than 30 days) to sample blood, administer fluids, and perform high pressure contrast injections at a maximum of 325 psi.

The Arrow™ Endurance™ Extended Dwell Peripheral Catheter System permits access to the patient's peripheral vascular system for short-term use (less than 30 days) to facilitate arterial blood pressure measurement and blood sampling.

The safety feature is intended to minimize the risk of sharps injuries.

The Arrow™ Endurance™ Extended Dwell Peripheral Catheter may be used for any patient population with consideration given to adequacy of anatomy and appropriateness of the procedure.

The Arrow™ Endurance™ Extended Dwell Peripheral Catheter may be used in hospitals, clinics, and other advanced clinical facilities.

7. Technological Characteristics

The Arrow™ Endurance™ Extended Dwell Peripheral Catheter System is substantially equivalent to the predicate Arrow™ Endurance™ Extended Dwell Peripheral Catheter System (K163513) in terms of indications for use, intended use, design, functional performance and materials of construction.

Features	Subject Device: Arrow™ Endurance™ Extended Dwell Peripheral Catheter System	Predicate Device Arrow™ Endurance™ Extended Dwell Peripheral Catheter System **(K163513)**	Assessment of Device Differences
Intended Use	The Arrow™ Endurance™ Extended Dwell Peripheral Catheter System is intended to access to the patient's peripheral vascular system for short-term venous or short-term arterial use.	The Arrow™ Endurance™ Extended Dwell Peripheral Catheter System is intended to access to the patient's peripheral vascular system for short-term venous or short-term arterial use.	Same
Indication for Use	The Arrow™ Endurance™ Extended Dwell Peripheral Catheter System permits access to the	The ARROW Endurance catheter system permits access to the patient's peripheral vascular system for short-	Different The subject device IFU separates

Features	Subject Device: Arrow™ Endurance™ Extended Dwell Peripheral Catheter System	Predicate Device Arrow™ Endurance™ Extended Dwell Peripheral Catheter System **(K163513)**	Assessment of Device Differences
	patient's peripheral vascular system for short-term venous use (less than 30 days) to sample blood, administer fluids, administer blood and blood products, and for high pressure contrast injections at a maximum of 325 psi. The Arrow™ Endurance™ Extended Dwell Peripheral Catheter System permits access to the patient's peripheral vascular system for short-term use (less than 30 days) to facilitate arterial blood pressure measurement and blood sampling. The safety feature is intended to minimize the risk of sharps injuries. The Arrow™ Endurance™ Extended Dwell Peripheral Catheter may be used for any patient population with consideration given to adequacy of anatomy and appropriateness of the procedure. The Arrow™ Endurance™ Extended Dwell Peripheral Catheter may be used in hospitals, clinics, and other advanced clinical facilities.	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.	peripheral vascular system into Vascular and Arterial usage and added the patient population and usage environment. While there is a difference in granularity, the intended use and indications for use of the subject device is similar. The difference does not raise new or different questions of safety and effectiveness.
Single Use	Yes	Yes	Same
Duration of Use	Less than 30 days	Less than 30 days	Same
Insertion	Gain vascular access with needle,	Gain vascular access with needle,	Same

Features	Subject Device: Arrow™ Endurance™ Extended Dwell Peripheral Catheter System	Predicate Device Arrow™ Endurance™ Extended Dwell Peripheral Catheter System **(K163513)**	Assessment of Device Differences
Technique	advance guide wire, advance catheter, remove needle and guidewire, deploy needle safety	advance guide wire, advance catheter, remove needle and guidewire, deploy needle safety	
Principle of Operation	The catheter is a closed fluid path system that consists of an insertion platform and a catheter.	The catheter is a closed fluid path system that consists of an insertion platform and a catheter.	Same
Shelf Life	6 months	2 years	Different Based on business needs and does not affect substantial equivalence. Bench testing and labeling support that there are no new safety or effectiveness concerns. See Nonclinical Testing.
MR Safety	MR Safe (catheter)	MR Safe (catheter)	Same
Device Design Feature			
Device Components	Includes Guard, Handle, Advancer, Slider, Needle Supports, Needle Safety, Extension Line Clamp, Needle, Guide Wire, Juncture Hub, Catheter with Extension Line	Includes Guard, Handle, Advancer, Slider, Needle Supports, Needle Safety, Extension Line Clamp, Needle, Guide Wire, Juncture Hub, Catheter with Extension Line	Same
Device Materials	Guard - Polypropylene Handle – Polycarbonate Advancer – Polycarbonate Slider –ABS Needle Supports – Polycarbonate Needle Safety – Stainless Steel Extension Line Clamp – Acetal	Guard - Polypropylene Handle – Polycarbonate Advancer – Polycarbonate Slider –ABS Needle Supports – Polycarbonate Needle Safety – Stainless Steel Extension Line Clamp – Acetal	Different The catheter body and coating and Extension Line Clamp materials are different. Biocompatibility and bench top testing demonstrate the difference does not raise new or different questions of safety and effectiveness.

Features	Subject Device: Arrow™ Endurance™ Extended Dwell Peripheral Catheter System	Predicate Device Arrow™ Endurance™ Extended Dwell Peripheral Catheter System **(K163513)**	Assessment of Device Differences
	Needle – Stainless Steel Guide Wire – Nitinol Juncture Hub – Polyurethane Extension Line - Polyurethane Luer Hub - Polyurethane Catheter Body– Quadraflex Polyurethane with Silicone Coating	Needle – Stainless Steel Guide Wire – Nitinol Juncture Hub – Polyurethane Extension Line - Polyurethane Luer Hub - Polyurethane Catheter Body – Tecoflex Polyurethane	
Catheter Design Configuration	The insertion platform consists of an ergonomically designed polycarbonate handle, an integral echogenic needle with openings to enhance flashback visibility to confirm placement in the vessel, a passive needle safety mechanism, a needle support to aid in insertion, and a guide wire with a slider advancer.	The insertion platform consists of an ergonomically designed polycarbonate handle, an integral echogenic needle with openings to enhance flashback visibility to confirm placement in the vessel, a passive needle safety mechanism, a needle support to aid in insertion, and a guide wire with a slider advancer.	Same
Catheter Body OD	20 Ga, 22 Ga	18 Ga, 20 Ga, 22 Ga	Different The subject device does not include 18Ga
Catheter Body ID	0.032” (20 Ga) 0.027” (22 Ga)	0.039” (18 Ga) 0.032” (20 Ga) 0.027” (22 Ga)	Different The subject device does not include 18Ga
Catheter Usable Length	6 cm (2.36”) 8 cm (3.15”)	6 cm (2.36”) 8 cm (3.15”)	Same
Needle Safety Feature	Yes	Yes	Same

Features	Subject Device: Arrow™ Endurance™ Extended Dwell Peripheral Catheter System	Predicate Device Arrow™ Endurance™ Extended Dwell Peripheral Catheter System **(K163513)**	Assessment of Device Differences
Blood Safety Feature	Bloodless (seal and extension lines)	Bloodless (seal and extension lines)	Same
Pressure Injection Limits	325 psi	325 psi	Same
Sidearm Clamp	Pinch	Slide	Different A different clamp has no impact on substantial equivalence. Bench testing supports that there are no new safety or effectiveness concerns. See Nonclinical Testing.
Juncture Hub Advancer	Half Circle Suture Wing Posts Removed Hub Nose Clips	Round Suture Wing Posts Hub Nose Clips	Different Juncture hub advancer design changes have no impact on substantial equivalence. Bench testing supports that there are no new safety or effectiveness concerns. See Nonclinical Testing.
Handle	Lower needle support No Catheter Release Tab	No Lower Needle Support Catheter Release Tab	Different Handle design changes have no impact on substantial equivalence. Bench testing supports that there are no new safety or effectiveness concerns. See Nonclinical Testing.
Catheter Body Material	Quadraflex Polyurethane	Tecoflex Polyurethane	Different The difference in the catheter body material has no impact on the use or functionality of the subject Endurance™ Catheter per its intended use as demonstrated by bench and biocompatibility testing, supporting that there are no new safety or effectiveness concerns. See Nonclinical Testing.
Coating	MDX Silicone	None	Different

Features	Subject Device: Arrow™ Endurance™ Extended Dwell Peripheral Catheter System	Predicate Device Arrow™ Endurance™ Extended Dwell Peripheral Catheter System **(K163513)**	Assessment of Device Differences
			The addition of a coating has no impact on the use or functionality of the subject Endurance™ Catheter per its intended per its intended use as demonstrated by bench and biocompatibility testing, supporting that there are no new safety or effectiveness concerns. See Nonclinical Testing.
Sterilization			
Sterile	Yes	Yes	Same
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Same
Biocompatibility			
Biocompatibility	Biocompatible materials used (per ISO 10993-1) Contact Type: Externally Communicating, Circulating Blood Duration: Prolonged (>24 hrs. and ≤30 days)	Biocompatible materials used (per ISO 10993-1) Contact Type: Externally Communicating, Circulating Blood Duration: Prolonged (>24 hrs. and ≤30 days)	Same

8. Nonclinical Testing

Bench testing performed on the Arrow™ Endurance™ Extended Dwell Peripheral Catheter System supports substantial equivalence of the subject devices. The following testing has been completed for the subject devices:

- Surface (Extraneous Mater and Defects & Lubricant)
- Wire Guide Advancement Length
- Catheter MR Compatibility
- Device Center of Gravity
- Latex, DEHP, and BPA Content
- Catheter Body Fluid Visualization
- Inactivated Extension Line Clamp
- Catheter Body Markings
- Peak Removal Force
- Catheter/ Needle Transition Insertion Force
- Needle Support
- Wire Guide Advancement Force
- Blood Flash
- Catheter Insertion tip damage
- Catheter column strength
- Catheter Tensile Force
- Catheter Tensile Elongation
- Catheter Body Kink
- Catheter Body to Juncture Hub Kink
- Gravity Flow Rate
- Repeat Pressure Injection (Flow Rate)
- Static Burst pressure under pressure injection
- Catheter Liquid Leakage
- Catheter Air Leakage
- Extension line Clamp Closure Efficacy
- Blood Draw Rate
- Pumped Flow Rate
- Arterial Blood Pressure Monitoring
- Catheter Body Softening
- Catheter Body Drag Force
- Particulate
- Needle Support
- Needle Strength of Union
- Clamp Force

9. Conclusion

The described intended use, results of verification testing performed, comparison of design and fundamental technology and comparison testing to the predicate device demonstrate that the subject device, Arrow™ Endurance™ Extended Dwell Peripheral Catheter System is substantially equivalent to the legally marketed predicate device, Arrow™ Endurance™ Extended Dwell Peripheral Catheter System (K163513). Any differences between the subject devices and predicate device do not raise new or different questions of safety and effectiveness.