September 2, 2022

Arrow International LLC Subsidiary of Teleflex Incorporated
Kim Pennington
Regulatory Affairs Specialist
3015 Carrington Mill Blvd
Morrisville, North Carolina 27560

Re: K213855
Trade/Device Name: Arrow® Pressure Injectable Midline Catheter
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: Class II
Product Code: PND
Dated: August 2, 2022
Received: August 3, 2022

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 (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 located 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.

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

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 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,

David Wolloscheck, Ph.D.
For Payal Patel
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)*

K213855

Device Name
Arrow® Pressure Injectable Midline

Indications for Use *(Describe)*

The Arrow(R) Pressure Injectable Midline Catheter is indicated for short-term (≤ 30 days) peripheral access to the venous system for intravenous therapy, blood sampling, infusion, and pressure injection of contrast media. The maximum pressure of pressure injector equipment used with the Arrow Pressure Injectable Midline Catheter may not exceed 300 psi (2068.4 kPa). The maximum pressure injection flow rate for the specific lumen being used for pressure injection is printed on the extension line hub.

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 – K213855

1. Submitter Information

Name:	Arrow International LLC, Subsidiary of Teleflex Incorporated
Address:	3015 Carrington Mill Blvd Morrisville, NC 27560
Telephone Number:	(610) 451-3095
Contact Peron:	Kim Pennington Regulatory Affairs Specialist
Email:	kim.pennington@teleflex.com
Date Prepared:	August 31, 2022

2. Device Name

Device Trade Name:	Arrow® Pressure Injectable Midline Catheter
Common Name:	Midline Catheter
Classification Name:	Intravascular catheter
Regulation:	21 CFR 880.5200
Product Code:	PND
Class:	II

3. Predicate Devices

K161313: Arrow Pressure Injectable Midline Catheter with ArrowG+ard Blue Advance Antimicrobial and Antithrombogenic Technology

4. Purpose

The purpose of this premarket notification is for the introduction to market of a sterile, single-use pressure injectable midline catheter without antimicrobial and antithrombogenic technology.

5. Device Description

The Arrow Pressure Injectable Midline Catheter is a non-coated, single use catheter designed to provide short-term peripheral access to the venous system. The midline catheter is a peripherally inserted intravenous catheter manufactured with medical grade, flexible polyurethane. It consists of a non-tapered, radiopaque polyurethane extruded catheter body with a single opening or double opening at the distal end and centimeter markings placed along its length to facilitate its positioning. The catheter is available in 4

Fr. Single lumen and 5 Fr. Double lumen configurations with a usable catheter length of 20 cm. Pinch clamps are an integral part of the catheter and are provided on the extension lines to occlude flow through the lumens, as needed. The catheters can be used for the injection of contrast media. The maximum recommended infusion rate is 5 mL/sec.

The catheters will be packaged sterile in kits that will include components to facilitate insertion.

6. **Intended Use**

The Pressure Injectable Midline Catheters are intended for short-term peripheral access to the venous system for intravenous therapy and blood sampling.

7. **Indications for Use**

The Arrow(R) Pressure Injectable Midline Catheter is indicated for short-term (≤ 30 days) peripheral access to the venous system for intravenous therapy, blood sampling, infusion, and pressure injection of contrast media. The maximum pressure of pressure injector equipment used with the Arrow Pressure Injectable Midline Catheter may not exceed 300 psi (2068.4 kPa). The maximum pressure injection flow rate for the specific lumen being used for pressure injection is printed on the extension line hub.

8. **Technological Characteristics and Substantial Equivalence**

The subject device is substantially equivalent to the predicate device:

Features	Subject Device: Arrow Pressure Injectable Midline Catheter K213855	Arrow Pressure Injectable Midline Catheter with ArrowG+ard Blue Advance Antimicrobial and Antithrombogenic Technology (K161313)	Assessment of Device Differences
Classification Name	Intravascular catheter	Intravascular catheter	Same
Product Code	PND	PND	Same
Regulation Number	880.5200	880.5200	Same
Class	II	II	Same
Indications for Use	The Arrow(R) Pressure Injectable Midline Catheter is indicated for short-term (≤ 30 days) peripheral access to the venous system for intravenous therapy, blood sampling, infusion, and pressure injection of contrast media. The maximum pressure of pressure injector equipment used with the Arrow Pressure Injectable Midline Catheter may not exceed 300 psi (2068.4 kPa). The maximum pressure injection flow rate for the specific lumen being used for pressure injection is printed on the extension line hub.	The Arrow ® Pressure Injectable Midline Catheter with Chlorag+ard® Antimicrobial and Antithrombogenic Technology is indicated for short-term (<30 days) peripheral access to the venous system for intravenous therapy, blood sampling, infusion, and pressure injection of contrast media. The maximum pressure of pressure injector equipment used with the Arrow Antimicrobial and Antithrombogenic Pressure Injecatable Midline Catheter may not exceed 300 psi (2068.4 kPa). The maximum pressure injection flow rate for the specific lumen being used for pressure injection is printed on the extension line hub. Chlorag+ard Technology treatment on the external surface of the catheter body as well as the entire fluid pathway of the catheter has been shown to be effective in reducing microbial colonization and thrombus accumulation on the catheter surfaces. Antimicrobial and antithrombogenic effectiveness was evaluated using in vitro and in vivo test methods and no correlation between these testing methods and clinical outcome has currently been ascertained. It is not intended to be used for the treatment of existing infections or vein thrombosis.	Different The subject device IFU is the same as the predicate device. The predicate device differs in that the device is coated with an antimicrobial and antithrombogenic technology on the internal luminal and outer catheter surface. The subject device is non-coatings on or within the catheter. The subject device.
Single Use	Yes	Yes	Same

Population	Adult	Adult	Same

Features	**Subject Device: Arrow Pressure Injectable Midline Catheter K213855**	**Arrow Pressure Injectable Midline Catheter with ArrowG+ard Blue Advance Antimicrobial and Antithrombogenic Technology (K161313)**	**Assessment of Device Differences**
Device Design Feature			
Lumens	Single and Double Lumen	Single and Double Lumen	Same
Internal Lumen Configuration	Round and Double D	Round and Double D	Same
Pressure Injection Capabilities	5 mL/sec	5 mL/sec	Same
Catheter Body OD	4 Fr – Single Lumen 5 Fr – Double Lumen	4.5 Fr – Single Lumen 5.5 Fr – Double Lumen	Different Justification for no S&E impact: The smaller catheter body OD has no impact on the use or functionality of the subject pressure injectable midline catheter per its intended use as demonstrated by appropriate testing in compliance with BS EN ISO 10555-1: 2013, ASTM F640-20, BS EN ISO 13868: 2002, and internal test methods for collapse resistance and blood draw which supports that there are no new safety or efficacy concerns.
Catheter Usable Length	20 cm	15 cm	Different Justification for no S&E impact: The difference in the catheter usable length has no impact on the use or functionality of the subject pressure injectable

			midline catheter per its intended use as demonstrated by appropriate testing in compliance with BS EN ISO 10555-1: 2013, ASTM F640-20, BS EN ISO 13868: 2002, and internal test methods for collapse resistance and blood draw which supports that there are no new safety or efficacy concerns.
Catheter Body Material	Clear Polyurethane with radiopacifier	Blue Polyurethane with radiopacifier	Different Justification for no S&E impact: The difference in the catheter body material has no impact on the use or functionality of the subject pressure injectable midline catheter per its intended use as demonstrated by appropriate testing in compliance with BS EN ISO 10555-1: 2013, ASTM F640-20, BS EN ISO 13868: 2002, BS EN ISO 10993-1: 2020, and internal test methods for collapse resistance and blood draw which supports that there are no new safety or efficacy concerns.
Radiopaque	Yes	Yes	Same
Catheter Body Printing Ink	Black Ink	Black Ink	Same
Catheter Tip Material	No Tip	Blue Flex Tip	Different Justification for no S&E impact: The difference in the catheter tip material has no impact on the use or functionality of the subject pressure injectable midline catheter per

			its intended use as demonstrated by appropriate testing in compliance with BS EN ISO 10555-1: 2013, BS EN ISO 10993-1: 2020, and internal test for collapse resistance and blood draw which supports that there are no new safety or efficacy concerns.
Juncture Hub Material	polyether polyurethane	polyether polyurethane	Same
Extension Line Material	natural polyurethane	natural polyurethane	Same
Extension Line Length	Approximately ¾" longer to accommodate the larger pinch clamps	Shorter by approximately ¾"	Different Justification for no S&E impact: The difference in extension line length has no impact on the use or functionality of the subject pressure injectable midline catheter per its intended use as demonstrated by appropriate testing in compliance with BS EN ISO 10555-1: 2013 and internal test for collapse resistance and blood draw which supports that there are no new safety or efficacy concerns.
Extension Line Markings	"18 GA"	"Midline – Proximal" "Midline – Distal"	Different Justification for no S&E impact: The difference in the extension line markings has no impact on the use or functionality of the subject pressure injectable midline catheter per its intended use as demonstrated by appropriate testing in compliance with BS EN ISO 10555-1:

			2013 which supports that there are no new safety or efficacy concerns.
Extension Line Hub Material	Yellow and white thermoplastic polyurethanes	Pink and white thermoplastic polyurethanes	Different Justification for no S&E impact: The difference in the extension line hub material has no impact on the use or functionality of the subject pressure injectable midline catheter per its intended use as demonstrated by appropriate testing in compliance with BS EN ISO 80369-7: 2016 and BS EN ISO 10993-1: 2020 which supports that there are no new safety or efficacy concerns.
Extension Line Hub Markings	"Midline" and "Max PI 5 mL/sec"	"Distal" and "Proximal" "Max 5 mL/sec" and "No CT"	Different Justification for no S&E impact: The difference in extension line hub markings has no impact on the use or functionality of the subject pressure injectable midline catheter per its intended use as demonstrated by appropriate testing in compliance with BS EN ISO 10555-1: 2013 which supports that there are no new safety or efficacy concerns.
Extension Line Clamp	Pinch Clamp	Slide Clamp	Different Justification for no S&E impact: The difference in the extension line clamp has no impact on the use or functionality of the subject pressure injectable midline catheter per its intended use as

			demonstrated by appropriate testing in compliance with BS EN ISO 10993-1: 2020 and internal test methods for extension line clamp closure efficacy and clamp force which supports that there are no new safety or efficacy concerns.
Shelf Life and Packaging			
Packaging	PET/LDPE film mated with Tyvek	PET/LDPE film mated with Tyvek	Same
Shelf Life	2 years	2 years	Same
Sterilization			
Sterile	Yes	Yes	Same
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Same

9. Nonclinical Testing

Non-clinical testing related to the device changes has been completed to support the substantial equivalence of the of the subject devices to the predicate devices.

9.1 Performance Testing

Testing	Standard
Luer Hub Testing • Material • Sub-atmospheric pressure air leakage • Stress Cracking/ Fluid Leakage • Resistance to separation from axial load • Resistance to separation from unscrewing • Resistance to overriding	BS EN ISO 80369-7: 2016
Labeling • Catheter Nominal Effective Length • Catheter outside diameter • Pressure Injection • Gravity flow Rate Visual Inspection • Surface Quality Mechanical Testing • Force at Break – Juncture Hub and Catheter Body • Force at Break – Luer Hub and Extension Line • Catheter Body Elongation • Catheter Navigation • Liquid Leakage under Pressure • Air Leakage during Aspiration • Priming Volume • Pump Flow Rate	BS EN ISO 10555-1: 2013

Testing	Standard
Pressure Injection • Flow rate under Pressure Injection/ Repeat Pressure Injection • Static Burst under Pressure Injection	
Radiopacity	ASTM F640-20
Catheter Body Kink	BS EN ISO 13868: 2002
Collapse Resistance	Internal Test Method
Blood Draw	Internal Test Method
Extension Line Clamp Closure Efficacy	Internal Test Method
Clamp Force	Internal Test Method

9.2 Biocompatibility Testing

Testing	Standard
Biocompatibility • Cytotoxicity • Sensitization • Irritation • Material Mediated Pyrogenicity • Acute Systemic Toxicity • Subacute Systemic Toxicity • Hemocompatibility • Genotoxicity • Chemical Characterization	BS EN ISO 10993-1: 2020

9.3 Sterilization, Shipping, and Sterile Barrier Testing

Testing	Standard
Sterilization Evaluation • Bacterial Endotoxin	ANSI/AAMI/ST72:2019
Sterilization Evaluation • Ethylene Oxide Residuals	BS EN ISO 10993-7: 2008
Preconditioning • Shipping • Distribution Simulation	 ISTA 3A ASTM D4169
Package Protection Testing	BS EN ISO 11607-1: 2020

10. Conclusions

The subject Arrow Pressure Injectable Midline Catheter has the same intended use as the stated predicate device and similar indications for use and technological characteristics. Any differences in technological characteristics do not raise different questions of safety and effectiveness compared to those applicable to the predicate device and do not pose a significant safety or effectiveness concern for the subject device.