DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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August 24, 2016

Arrow International, Inc. (subsidiary of Teleflex Inc.)
Ms. Julie Lawson
Regulatory Affairs Specialist
2400 Bernville Road
Reading, Pennsylvania 19605

Re: K161313
Trade/Device Name: Arrow® Pressure Injectable Midline Catheter with Chlorag+ard® Antimicrobial and Antithrombogenic Technology
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: PND
Dated: July 22, 2016
Received: July 25, 2016

Dear Ms. Lawson:

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 yours,

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)*
K161313

Device Name
- ARROW Pressure Injectable Midline Catheter with Chlorag+ard Antimicrobial and Antithrombogenic Technology

Indications for Use *(Describe)*
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 Injectable Midline Catheter may not exceed 300 psi (2068.4kPa). 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 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.

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

ARROW PRESSURE INJECTABLE MIDLINE CATHETER
WITH CHLORAG+ARD ANTIMICROBIAL AND ANTITHROMBOGENIC TECHNOLOGY

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 Person:	Julie Lawson Regulatory Affairs Specialist
Telephone Number:	(610) 378-0131 Extension 603256
Fax Number:	(610) 478-3179
Email:	julie.lawson@teleflex.com

Date Prepared: May 9, 2016

2. Device Name

Device Trade Name:	Arrow® Pressure Injectable Midline Catheter with Chlorag+ard® Antimicrobial and Antithrombogenic Technology
Common Name:	Midline Catheter
Regulation Number:	21 CFR: 880.5200
Regulation Name:	Intravascular Catheter

Product Code: PND

3. Predicate and Reference Devices

Arrow Peripherally Inserted Midline Catheter (K963257) - Predicate

ArrowEvolution™ Pressure Injectable PICC with Chlorag+ard Antimicrobial and Antithrombogenic Technology (K112896) - Reference

4. Device Description

The Arrow Pressure Injectable Midline Catheter with Chlorag+ard Antimicrobial and Antithrombogenic Technology is a single use catheter designed to provide short-term peripheral access to the venous system. It consists of a non-tapered, radiopaque polyurethane extruded catheter body with a softer, contoured Blue FlexTip (flexible distal tip). The catheter is available in 4.5 Fr. Single lumen and 5.5 Fr. Double lumen configurations with a usable catheter length of 15 cm. The catheters can be used for the injection of contrast media. The maximum recommended infusion rate is 5 mL/sec. The external catheter body and the entire internal fluid path of the device are treated with a Chlorhexidine-based solution

technology. Studies have shown the technology to possess both antimicrobial and antithrombogenic properties.

The catheters will be packaged sterile in kits that will include components to facilitate insertion. The Chlorag+ard technology that is incorporated in the modified device's physical design is the same as the reference device.

5. Indications for Use

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 Injectable Midline Catheter may not exceed 300 psi (2068.4kPa). 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 catheter surfaces. Antimicrobial and antithrombogenic effectiveness were 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 or vein thrombosis.

6. Technological Characteristics and Substantial Equivalence

The Arrow Pressure Injectable Midline Catheter with Chlorag+ard Antimicrobial and Antithrombogenic Technology is substantially equivalent to the predicate Arrow Peripherally Inserted Midline Catheter (K963257) in terms of Indications for use. Both the predicate and the subject Indications for Use refer to use for peripheral access to the venous system. The difference in the Indications for use is that the subject Indications for use specifies in more detail the uses for the device and includes the ability to use the device for pressure injection as well as describing the antimicrobial and antithrombogenic properties of the subject catheter. (The predicate device does not contain antimicrobial and antithrombogenic properties.)

The Arrow Pressure Injectable Midline Catheter with Chlorag^{+}ard Antimicrobial and Antithrombogenic Technology is substantially equivalent to the reference device, the ArrowEVOLUTION™ Pressure Injectable PICC with Chlorag^{+}ard Antimicrobial and Antithrombogenic Technology (K112896) in terms of overall design, manufacturing process, functional performance, and materials of construction. The indications for use for the subject catheter are the same as the reference device (K112896) in all aspects aside from providing central venous access and the ability to use the device

for central venous pressure monitoring. The tip of the reference device (K112896) is intended to terminate in the Superior Vena Cava (central venous system) whereas the tip of the subject device is intended to terminate below the axillary line (venous system).

The same Chlorag+ard Technology treatment that is used for the reference device, the ArrowEVOLUTION™ Pressure Injectable PICC with Chlorag+ard Antimicrobial and Antithrombogenic Technology (K112896) is used for the subject device. The process of application of the Chlorag+ard Technology treatment is also the same as that of the reference device.

Predicate, Reference and Subject Device Comparison

Design Characteristic	Predicate Device Arrow Peripherally Inserted Midline Catheter (K963257)	Reference Device AM/AT PICC (K112896)	Subject Pressure Injectable CG+ MIDLINE
Intended Use	The Midline Catheter permits venous access to the peripheral circulation. It offers an alternative method of intravenous access for select adult and pediatric patients.	The Pressure Injectable Peripherally Inserted Central Catheters are intended for short-term or long-term peripheral access to the central venous system for intravenous therapy and blood sampling.	The Pressure Injectable Midline Catheters are intended for short-term peripheral access to the venous system for intravenous therapy and blood sampling.
Indications for Use	The Midline Catheter permits venous access to the peripheral circulation. It offers an alternative method of intravenous access for select adult and pediatric patients.	The ArrowEVOLUTION™ Pressure Injectable PICC with Chlorag^{+}ard Antimicrobial and Antithrombogenic Technology is indicated for short-term or long-term peripheral access to the central venous system for intravenous therapy, blood sampling, infusion, pressure injection of contrast media, and allows for central venous pressure monitoring. The maximum pressure of pressure injector equipment used with the ArrowEVOLUTION™	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

Design Characteristic	Predicate Device Arrow Peripherally Inserted Midline Catheter (K963257)	Reference Device AM/AT PICC (K112896)	Subject Pressure Injectable CG+ MIDLINE
		Pressure Injectable PICC may not exceed 300 psi. 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 catheter surfaces. Antimicrobial and antithrombogenic effectiveness were 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.	Pressure Injectable Midline Catheter may not exceed 300 psi (2068.4kPa). 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 catheter surfaces. Antimicrobial and antithrombogenic effectiveness were 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.
Catheter OD	3, 4 and 5 Fr	4.5 Fr and 5.5 Fr	Same as reference device: 4.5 Fr and 5.5 Fr.
Catheter Usable Length	15 cm	40, 50, and 55 cm	Same as predicate device: 15 cm.

Design Characteristic	Predicate Device Arrow Peripherally Inserted Midline Catheter (K963257)	Reference Device AM/AT PICC (K112896)	Subject Pressure Injectable CG+ MIDLINE
Number of Lumens	3, 4 and 5 Fr. - 1 lumen 4 and 5 Fr. - 2 lumens	4.5 Fr. – 1 lumen 5.5 Fr. – 2 lumens	Same as reference device: 4.5 Fr. – 1 lumen 5.5 Fr. – 2 lumens
Internal Lumen Configuration	Round Circle/crescent	4.5 Fr. – Round 5.5 Fr. – Double D	Same as reference device: 4.5 Fr. – Round 5.5 Fr. – Double D
Catheter Tip Configuration	Blunt Tip	Blue FlexTip	Same as reference device: Blue FlexTip
Pressure Injection Capabilities	None	**Distal** lumen– 5 mL/sec, Pressure Injectable **Proximal** lumen– 5 mL/sec, Pressure Injectable	**Distal** lumen – 5 mL/sec, Pressure Injectable **Proximal** lumen– Not labeled for Pressure Injection
Chlorhexidine -Based Coating Performance	None	Antimicrobial Efficacy Effective in reducing microbial colonization Antithrombogenic Efficacy Effective in reducing thrombus accumulation	Same as reference device: Antimicrobial Efficacy Effective in reducing microbial colonization Antithrombogenic Efficacy Effective in reducing thrombus accumulation
Catheter Body Material	White Polyurethane with 20% Barium Sulfate	Blue Polyurethane with 30% Bismuth Oxychloride	Same as reference device: Blue Polyurethane with 30% Bismuth Oxychloride
Catheter Tip Material	White Polyurethane with 20% Barium Sulfate	Blue Polyurethane with 30% Bismuth Oxychloride	Same as reference device: Blue Polyurethane with 30% Bismuth Oxychloride
Juncture Hub Material	White Polyurethane	Transparent Light Blue Polyurethane	Same as reference device: Transparent Light Blue Polyurethane
Extension Line	Clear Polyurethane	Clear Polyurethane	Same as reference device:

Design Characteristic	Predicate Device Arrow Peripherally Inserted Midline Catheter (K963257)	Reference Device AM/AT PICC (K112896)	Subject Pressure Injectable CG+ MIDLINE
Material			Clear Polyurethane
Extension Hub Material	Natural Polyurethane	**Distal** – Pink Polyurethane **Proximal** – White Polyurethane	Same as reference device: **Distal** – Pink Polyurethane **Proximal** – White Polyurethane
Printing Ink	Printing Ink NT16 Black Ink Black Hot Stamp Printing Foil	Printing Ink 2405 Black Ink	Same as reference device: Printing Ink 2405 Black Ink
Safety and Performance Testing	Mechanical testing to: • ISO 10555-1 • ISO 10555-3 Biocompatibility testing	Mechanical testing to: • ISO 10555-1 • ISO 10555-3 Biocompatibility testing	Same as both predicate and reference device: Mechanical testing to: • ISO 10555-1 • ISO 10555-3 Biocompatibility testing

7. Nonclinical Testing

The following performance testing related to the device changes has been completed to support the substantial equivalence of the subject devices to the predicate and reference devices:

- priming volume
- gravity flow rate
- 10 psi pumped flow rate
- rate limited pressure injection
- pressure limited injection
- static burst
- mechanical hemolysis
- tensile testing (extension line to luer hub)

The following standards were used in the non-clinical testing listed above:

- ASTM F756-08
- ISO 10555-1
- ISO 10555-3
- ISO 10993-7
- ISO 11135

8. Conclusions

The Arrow Pressure Injectable Midline Catheter with Chlorag^{+}ard Antimicrobial and Antithrombogenic Technology is the same device as the reference device, the ArrowEVOLUTION Pressure Injectable PICC with Chlorag^{+}ard Antimicrobial and Antithrombogenic Technology (K112896) with the exception of usable catheter length, extension line hub design (on proximal lumen of 2 lumen midline catheter) and extension line text. The results of the testing performed have demonstrated that the devices are safe, effective, and perform as intended. The subject device and predicate and reference devices (K963257 and K112896 respectively) have the same insertion site and associated insertion procedure. The final indwelling tip position of the subject and predicate (K963257) device is the same because they are both midline catheters per the proposed indications for use.

In conclusion, the Arrow Pressure Injectable Midline Catheter with Chlorag^{+}ard Antimicrobial and Antithrombogenic Technology is substantially equivalent to the predicate Arrow Peripherally Inserted Midline Catheter (K963257) and the reference device, the ArrowEVOLUTION Pressure Injectable PICC with Chlorag^{+}ard Antimicrobial and Antithrombogenic Technology (K112896).