DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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September 6, 2016

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

Re: K161765
Trade/Device Name: ARROW Pressure-Injectable Jugular Axillo-Subclavian Central Catheter with Chlorag+ard Antimicrobial and Antithrombogenic Technology (CG+ Arrow JACC)
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long-Term Intravascular Catheter
Regulatory Class: II
Product Code: LJS
Dated: August 5, 2016
Received: August 8, 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,

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)*
K161765

Device Name
ARROW Pressure-Injectable Jugular Axillo-Subclavian Central Catheter with Chlorag+ard Antimicrobial and Antithrombogenic Technology (CG+ Arrow JACC)

Indications for Use *(Describe)*
The Arrow® Pressure Injectable Jugular Axillo-subclavian Central Catheter with Chlorag+ard® Antimicrobial and Antithrombogenic Technology (CG+ Arrow JACC) is indicated for short-term (<30 days) or long-term (>30 days) 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 Arrow Pressure Injectable JACC 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 on catheter surfaces. Antimicrobial 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.

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: K161765

Submitter Information

Name:	Arrow International, Inc (subsidiary of Teleflex Inc.)
Address:	2400 Bernville Road Reading, PA 19605-9607 USA
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:	June 24, 2016

Device Name

Device Trade Name: ARROW Pressure-Injectable Jugular Axillo-Subclavian Central Catheter with Chlorag+ard Antimicrobial and Antithrombogenic Technology (CG+ Arrow JACC)
Common Name: Central Venous Catheter
Classification Regulation: 21 CFR: 880.5970
Classification Name: Percutaneous, implanted, long-term intravascular catheter
Product Code: LJS

Predicate Device

K153423: CG+ Arrow JACC / CG+ Arrow JACC powered by Arrow VPS Stylet

Device Description

The Arrow® Pressure Injectable Jugular Axillo-subclavian Central Catheter with Chlorag+ard® Antimicrobial and Antithrombogenic Technology (CG+ Arrow JACC) has the following characteristics:

- 4.5 French, 1-Lumen, 35 cm pressure injectable, antimicrobial and antithrombogenic catheter
- 5.5 French, 2-Lumen, 35 cm pressure injectable, antimicrobial and antithrombogenic catheter
- 6 French, 3-Lumen, 35 cm pressure injectable, antimicrobial and antithrombogenic catheter

The CG+ Arrow JACC is a short-term or long-term, single use catheter designed to provide access to the central venous system. These catheters may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness of the procedure. The CG+ Arrow JACC consists of a non-tapered, radiopaque polyurethane extruded catheter body, a juncture hub, extension lines for each lumen and printed extension line hubs. The extension lines each contain a clamp. The catheter can be used for the injection of contrast media. The maximum recommended infusion rate is 5 mL/sec for the 1-lumen and 2-lumen catheters and 6 mL/sec for the 3-lumen catheter. The external catheter body and the internal fluid path of the device are treated with chlorhexidine–based, Chlorag+ard technology. There are no

modifications subject to this premarket notification related to the material design of the devices included in this submission, nor are there any modifications to the Chlorag+ard technology that is incorporated in the modified device's physical design.

The subject device is a CG+ Arrow JACC without a Blue FlexTip that will be provided in sterile kit configurations. A catheter-compatible tunneling device will be offered as an optional kit component. In addition to the catheter tip modification, the printed text on the catheter body and the extension lines has also been modified. These design modifications, as well as the addition of the tunneling device as an optional kit component, require additions to the recommended procedural technique; procedure steps related to the tunneler and updated graphic representation of the catheter have been included in the instructions for use. All other portions of the catheter design and instructions for use remain unchanged.

Indications for Use

The Arrow® Pressure Injectable Jugular Axillo-subclavian Central Catheter with Chlorag+ard® Antimicrobial and Antithrombogenic Technology (CG+ Arrow JACC) is indicated for short-term (<30 days) or long-term (>30 days) 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 Arrow Pressure Injectable JACC 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 on catheter surfaces. Antimicrobial 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.

The above Indication for Use is identical to the catheter portion of the predicate Indications for Use. The predicate CG+ Arrow JACC / CG+ Arrow JACC powered by Arrow VPS Stylet (K153423) includes a 2-part indications for use statement; the first portion covers the CG+ Arrow JACC and the second portion covers the CG+ Arrow JACC preloaded with the Arrow VPS Stylet. The subject of this submission is the CG+ Arrow JACC portion of the device only. The VPS-preloaded portion of the indications for use is not impacted by the changes described for the proposed CG+ Arrow JACC. Therefore, only the catheter portion of the indications for use statement for the proposed CG+ Arrow JACC is applicable.

Technological Characteristics and Substantial Equivalence

The subject CG+ Arrow JACC is substantially equivalent to the predicate CG+ Arrow JACC / CG+ Arrow JACC powered by VPS (K153423) in terms of indications for use (catheter portion), manufacturing processes, conditions and aids, functional performance, fundamental scientific technology and materials of construction. There is no change to the geometric design of the subject devices with the exception of the catheter tip: the predicate device is constructed with a

Blue FlexTip distal tip design and the catheter is trimmable; the proposed device omits the Blue FlexTip distal tip, yielding the same catheter distal tip design as the predicate device when trimmed. The instructions for use are being modified to add detail pertaining to the use of a tunneler; catheter trimming instructions were previously included in the instructions for use and continue to apply to the subject device. The following table reflects a comparison of the subject and predicate device characteristics.

Subject and Predicate Device Comparison

Characteristic	Predicate: CG+ Arrow JACC / CG+ Arrow JACC powered by VPS Stylet (K153423)	Subject: CG+ Arrow JACC
Catheter Length	15-35 cm	35 cm only
Catheter OD	4.5, 5.5, and 6 Fr	SAME
Number of Lumens	1,2, and 3 Lumen	SAME
Internal Lumen Configuration	1 Lumen - Round 2 Lumen – Double D 2 Lumen - Round-Crescent 3 Lumen- Round-Split-Crescent	1 Lumen - Round 2 Lumen – Double D 3 Lumen- Round-Split-Crescent
Pressure Injection Capabilities	1 Lumen: Distal:5 mL/sec. Pressure Injectable 2 Lumen - Double D: Distal: 5 mL/sec, Pressure Injectable Proximal: 5 mL/sec, Pressure Injectable 2 Lumen - Round-Crescent: Distal: 5 mL/sec, Pressure Injectable Proximal: 4 mL/sec, Pressure Injectable 3 Lumen: Distal: 6 ml/sec, Pressure Injectable Proximal: No Pressure Injection Medial: No Pressure Injection **Note:** Lumens that are not indicated for Pressure Injection have “No CT” printed on the extension line hubs.	1 Lumen: Distal:5 mL/sec. Pressure Injectable 2 Lumen - Double D: Distal: 5 mL/sec, Pressure Injectable Proximal: 5 mL/sec, Pressure Injectable 3 Lumen: Distal: 6 ml/sec, Pressure Injectable Proximal: No Pressure Injection Medial: No Pressure Injection **Note:** Lumens that are not indicated for Pressure Injection have “No CT” printed on the extension line hubs.
Catheter body material	Radiopaque polyurethane	SAME
Catheter Juncture Hub Material	Blue polyurethane	SAME
Catheter Tip Design and material	Radiopaque, soft blue polyurethane “Blue FlexTip”	Non Blue FlexTip; blunt tip (integral with and same material as the catheter body and equivalent to a trimmed predicate CG+ Arrow JACC)
Catheter trimmable?	Yes	Yes
Extension Line Material	Clear polyurethane	SAME

Characteristic	Predicate: CG+ Arrow JACC / CG+ Arrow JACC powered by VPS Stylet (K153423)	Subject: CG+ Arrow JACC
Extension Line Hub Material	Distal - Pink polyurethane Proximal – White Polyurethane Medial – Blue Polyurethane	SAME
Printing Ink	2405 Black Ink and White Ink	SAME
Sterilization	Provided Sterile. Sterilized by Ethylene Oxide.	SAME
Performance Specifications; Catheter treatment solution efficacy	Antimicrobial Efficacy Effective in reducing microbial colonization on catheter surfaces Antithrombogenic Efficacy Effective in reducing thrombus accumulation on catheter surfaces	SAME
Tunneler Compatibility	N/A	Can accommodate a tunneler accessory which is specifically designed for use with the catheter to facilitate the tunneled insertion technique.
Indications for Use	The Arrow® Pressure Injectable JACC with Chlorag+ard® Antimicrobial and Antithrombogenic Technology is indicated for short-term (<30 days) or long-term (>30 days) 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 Pressure Injectable JACC 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 on catheter surfaces. Antimicrobial 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. The VPS Stylet and Console are indicated for guidance and tip positioning for central venous catheters. The Stylet provides stiffness for use in placement of the catheter, intravascular capability for ECG detection and recording and intravascular ultrasound for catheter guiding and positioning. The VPS Stylet, when used with the VPS Console, provides real-time catheter tip location information by using the patient's physiological (cardiac electrical activity and blood flow) information. When the VPS System guidance indicator shows a Blue Bullseye, the catheter tip is in the desired location. The VPS System is indicated for use as an alternative method to fluoroscopy or chest x-ray for central venous catheter tip placement confirmation in adult patients when a steady Blue Bullseye is obtained. NOTE: If a steady Blue	The Arrow® Pressure Injectable JACC with Chlorag+ard® Antimicrobial and Antithrombogenic Technology is indicated for short-term (<30 days) or long-term (>30 days) 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 Pressure Injectable JACC 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 on catheter surfaces. Antimicrobial 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.

Characteristic	Predicate: CG+ Arrow JACC / CG+ Arrow JACC powered by VPS Stylet (K153423)	Subject: CG+ Arrow JACC
	Bullseye is not obtained, standard hospital practice should be followed to confirm catheter tip location. Limiting but not contraindicated situations for this technique are in patients where alterations of cardiac rhythm change the presentation of the P-wave as in atrial fibrillation, atrial flutter, severe tachycardia and pacemaker-driven rhythm, and in central venous catheterization procedures performed through femoral or saphenous vein access which change the presentation of the Pwave. In such patients, who are easily identifiable prior to central venous catheter insertion, the use of an additional method is required to confirm catheter tip location.	

Nonclinical Testing

Risk analysis activities were conducted to assess the impact of the modifications made to the subject device. Appropriate control mechanisms were defined to mitigate the identified risks. Design verification testing was conducted to mitigate identified risks and is summarized in the submission to support the substantial equivalence of the modified device. The following testing is summarized in the submission:

- Tunneler Device Testing
  - Biocompatibility - Cytotoxicity – L929 MEM Elution
  - Corrosion Resistance
  - Tip Penetration
  - Extraneous Matter
- Tunneler device/Catheter Compatibility
  - Tunneler detachment force from catheter
  - Catheter not damaged by tunnel disconnection
- Catheter Priming Volume (for labeling purposes only)

Conclusions

The predicate and the subject devices have the same indications for use (catheter portion), intended use, materials (with the exception of the elimination of the material used to form the Blue FlexTip), chlorhexidine formulation, concentration (content per treated surface area), method of application and mechanism of release and are manufactured using the same processes with the exception of the Blue FlexTip formation process, conditions and aids. The results of the verification testing performed support the substantial equivalence of the modified devices to the predicate devices.