

K100635

**510(k) SUMMARY**

**SUMMARY OF SAFETY AND EFFECTIVENESS  
FOR  
ARROW ANTIMICROBIAL PRESSURE INJECTABLE PICC**

**AUG 27 2010**

**1. Submitter Information**

Name: Arrow International, Inc (subsidiary of Teleflex Inc.)  
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Date Prepared: June 4, 2010

**2. Device Name**

Device Trade Name: Arrow Antimicrobial Pressure Injectable Peripherally  
Inserted Central Catheter (PICC)  
Common Name: Peripherally Inserted Central Catheter  
Classification Name: Percutaneous, implanted, long-term intravascular catheter

**3. Predicate Devices**

Predicate 1: Pressure Injectable PICC (K061289)  
Predicate 2: 6 French Triple Lumen Pressure Injectable PICC (K080604)  
Predicate 3: ARROWg<sup>+</sup>ard Blue PLUS<sup>®</sup> Multi-Lumen CVC (K993691)

**4. Device Description**

The Arrow Antimicrobial Pressure Injectable PICC is a short-term or long-term, single use catheter designed to provide access to the central venous system. It consists of a non-tapered, radiopaque polyurethane extruded catheter body with a softer, contoured Blue Flex Tip. The catheter is available in 4.5 Fr. single lumen and 5.5 Fr. double lumen configurations with usable lengths of 40 – 55 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 internal fluid path of the device are treated with Chlorhexidine based antimicrobial technology.

The catheters will be packaged sterile in both nursing and radiology configurations. Both configurations will include components to facilitate insertion.

## **5. Indications for Use**

The Arrow Antimicrobial Pressure Injectable PICC 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 Arrow Antimicrobial Pressure Injectable PICC may not exceed 300 psi. Antimicrobial 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. Antimicrobial effectiveness was evaluated using *in vitro* methods, and no correlation between *in vitro* and clinical outcome has currently been ascertained. It is not intended to be used for the treatment of existing infections.

## **6. Summary Comparing Technological Modifications**

Modifications to existing Arrow products include:

- Inclusion of 4.5 Fr. single lumen and 5.5 Fr double lumen catheters to those ARROW PICCs already marketed. The increase in OD of the catheters allow for the subject devices to achieve 5 mL/sec pressure injection and to accommodate external / internal treatment.
- The catheter body material for the subject devices consist of a blending of two durometers of polyurethane resin. A blue colorant was added to the catheter body resins to differentiate from non-antimicrobial PIC catheters.
- A blue colorant was added to the juncture hub material of the subject devices to further differentiate the antimicrobial catheters.
- The catheter tip material of the subject devices includes a different radiopacifier for enhanced radiopacity.
- Antimicrobial treatment has been applied to the external catheter body surface and the entire fluid path of the device.
- The antimicrobial treatment present on the external catheter body of the subject devices consist of chlorhexidine only as opposed to chlorhexidine and silver sulfadiazine present on currently marketed Arrowgard Blue Plus central venous catheters.

## **7. Nonclinical Testing**

Bench testing was performed on the Arrow Antimicrobial Pressure Injectable PICC in accordance with ISO 10555-1, 10555-3 and FDA Guidance on Premarket Notification [510(k)] Submission for Short- Term and Long- Term Intravascular Catheters. *In vitro* and *in vivo* testing was performed to assess the safety and efficacy of the proposed device. Testing included biocompatibility, *in vitro* antimicrobial efficacy, and *in vivo* animal infection study.

## 8. Summary of Verification Activities

Test	Acceptance Criteria	Results														
<b>Air Leakage during aspiration</b>	<p>There shall be no air leakage in the form of an air bubble in the syringe connected to the PICC after the first 5 seconds when tested per BS EN ISO 10555-1:1997 Annex D.</p> <p>All catheters must pass to achieve a 5% LTPD with 95% confidence</p>	Pass														
<b>Collapse Resistance</b>	<p>The catheter shall not collapse during aspiration as evidenced by water being able to be pulled out of the catheter when vacuum is applied by a minimum of a 10 cc syringe. The extension line clamps, if present, shall be in the fully constrained position.</p> <p>All catheters must pass to achieve a 5% LTPD with 95% confidence</p>	Pass														
<b>Liquid Leakage under pressure</b>	<p>There shall be no liquid leakage in the form of a falling drop of water at 300-320 kPa (43.5 -46.4) for 30 sec when tested per BS EN ISO 10555-1:1997 Annex C.</p> <p>All catheters must pass to achieve a 5% LTPD with 95% confidence</p>	Pass														
<b>Force at break -Tensile Testing and Catheter Elongation</b>	<p>There must be a 95% confidence level that 95% of the population meets the specification.</p> <table border="1"> <thead> <tr> <th>Tensile attribute</th> <th>Requirement per BS EN ISO 10555-1 and 10555-3</th> </tr> </thead> <tbody> <tr> <td>Catheter Body Force at Break</td> <td>≥ 10N</td> </tr> <tr> <td>Blue Flex Tip to Catheter Body Force at Break</td> <td>≥ 4N</td> </tr> <tr> <td>Catheter Body to Juncture Hub Force at Break</td> <td>≥ 10N</td> </tr> <tr> <td>Extension Line to Juncture Hub Force at Break</td> <td>≥ 15N</td> </tr> <tr> <td>Extension Line to Luer Hub Force at Break</td> <td>≥ 15N</td> </tr> <tr> <td>Catheter Body Elongation</td> <td>&gt; 100%</td> </tr> </tbody> </table>	Tensile attribute	Requirement per BS EN ISO 10555-1 and 10555-3	Catheter Body Force at Break	≥ 10N	Blue Flex Tip to Catheter Body Force at Break	≥ 4N	Catheter Body to Juncture Hub Force at Break	≥ 10N	Extension Line to Juncture Hub Force at Break	≥ 15N	Extension Line to Luer Hub Force at Break	≥ 15N	Catheter Body Elongation	> 100%	Pass
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Catheter Body Elongation	> 100%															
<b>Radio-Detectability</b>	The optical density contrast must be at least 0.1.	Pass														
<b>Catheter Body Kink</b>	Does not kink at a radius greater than 0.5 inch when tested per BS EN 13868:2002 Annex A under simulated <i>in vivo</i> conditions. This requirement shall be met with 95% assurance.	Pass														

Test	Acceptance Criteria	Results
<b>Central Venous Pressure Monitoring</b>	The average amplitude difference between input and output signals shall be less than or equal to 1 mmHg when tested using a 1 Hz sinusoidal input signal. This requirement shall be met with 95% assurance.	Pass
<b>Column Strength and Tip Stiffness</b>	<p>For catheters having a tip of different construction to the catheter body, the tip shall be constructed in accordance with the requirement 5.1.6 and shall be made of lower durometer material than that of the catheter body.</p> <p>Design of tip shall ensure that the average force required to deflect or compress the tip is no greater than the average force required to deflect or compress the catheter body.</p> <p>NOTE: Requirement 5.1.6 referenced above is taken from an internal Arrow requirements document. Requirement 5.1.6 is identical to the requirement found in ISO 10555-3 Section 4.3.</p>	Pass
<b>Static Burst Pressure</b>	The maximum internal static pressure during pressure injection shall not exceed the static burst pressure.	Pass
<b>Static Burst Pressure</b>	The maximum internal static pressure during pressure injection shall not exceed the static burst pressure.	Pass
<b>Rate Limited Injection Testing</b>	Each pressure injectable lumen shall withstand at least 5 repeat injections without rupture or visually evident yielding of the catheter when injected at the maximum indicated flow rate using 125 mL of contrast media or equivalent (maximum viscosity of $11.8 \pm 0.2$ cP) at $37 \pm 2^\circ\text{C}$ .	Pass
<b>Pressure Limited Injection Testing</b>	The average flow rate of each catheter lumen shall be at least 90% of the maximum indicated flow rate.	Pass
<b>Ink Adhesion Testing</b>	The catheter shall remain legible when examined without magnification with exposure to ChloroPrep and Iodine for 1 minute each, then application and removal of semi-permeable adhesive dressing and Biopatch after 7 days. The acceptance criteria for meeting this requirement will be a legible marking.	Pass
<b>Step Stress Testing</b>	The catheters shall pass the first 10 injections at the maximum flow rate without visually evident yielding or rupture.	Pass
<b>Trim Tool</b>	<p>After trimming with the provided trimming tool and visualized under 2.5X magnification, the indwelling catheter shall terminate at the distal end with a square tip that:</p> <ul style="list-style-type: none"> <li>• Has no points</li> <li>• Produces a clean, smooth surface</li> </ul> <p>With a sample size of <math>n=60</math>, zero failures are required to show a 95% confidence level and LTPD=5% in an attribute test.</p>	Pass

Test	Acceptance Criteria	Results
<b>Luer Hub Slip</b>	<p><u>Luer Hub Slip</u></p> <p>The hub shall meet the following Luer slip requirements with 95% confidence and a LTPD of 10% when tested per BS EN 20594-1:1994, ISO 594-1:1986 Clauses 5.1 through 5.5:</p> <p><b>Gauging:</b> The plane of the maximum diameter at the opening of the female conical fitting shall lie between the two limit planes of the gauge. Rocking shall not be evident between the gauge and the fitting made of rigid material undergoing test.</p> <p><b>Liquid Leakage:</b> No liquid leakage shall occur in the form of one or more falling drops of water.</p> <p><b>Air Leakage:</b> There shall be no signs of continued formation of air bubbles.</p> <p><b>Separation force:</b> The Luer hub shall remain attached to the reference fitting.</p> <p><b>Stress cracking:</b> There shall be no evidence of stress cracking of the fitting.</p>	Pass
<b>Luer Hub Lock</b>	<p><u>Luer Hub Lock</u></p> <p>The hub shall meet the following Luer lock requirements with 95% confidence and a LTPD of 10% when tested per BS EN 1707:1997 Clauses 5.2 through 5.8:</p> <p><b>Gauging:</b> When tested with the appropriate gauge, the conical part of the lock fitting shall have the plane of the maximum diameter at the opening of the female conical fitting shall lie between the two limit planes of the gauge. Rocking shall not be evident between the gauge and the fitting made of rigid material undergoing test.</p> <p><b>Liquid Leakage:</b> No liquid leakage shall occur in the form of one or more falling drops of water.</p> <p><b>Air Leakage:</b> There shall be no signs of continued formation of air bubbles.</p> <p><b>Separation force:</b> The Luer hub shall remain attached to the reference fitting.</p> <p><b>Unscrewing torque:</b> The Luer hub shall remain attached to the reference fitting.</p> <p><b>Ease of Assembly to Male Fitting:</b> No resistance shall be observed until the taper of the fitting under test and the reference fitting fit together securely.</p> <p><b>Resistance to Overriding Male to Female Luer Connection:</b> The reference fitting shall not override the threads or lugs of the fitting under test.</p> <p><b>Stress cracking:</b> There shall be no evidence of stress cracking of the fitting</p>	Pass
<b>Catheter Securement</b>	<p>The catheter shall include a feature that enables the catheter to be secured to the patient's skin.</p> <p>Demonstrate a 95% confidence level and LTPD=5% by having the suture holes for all catheters fit over the Securement posts with zero failures and the retainer wings from all catheters lock into place with zero failures.</p>	Pass

Test	Acceptance Criteria	Results
<b>First Article Inspection</b>	<p>If the catheter is provided with distance markings, the marking system shall indicate distance from the distal end. From the first mark, the distance between marks shall not exceed 5cm. (BS EN ISO 10555-3: 1997 Section 4.4 and JIS T 3218:2005, Section 5.7)</p> <p>For multilumen catheters, identification of each lumen shall be apparent to the user (BS EN ISO 10555-3:1997, Item 4.5 and JIS T 3218:2005, Item 5.8)</p> <p>The French size of the catheter shall be printed on the integral juncture hub or in a location that can be seen after the catheter has been inserted.</p> <p>The tradename and/or name of the manufacturer of the catheter shall be printed on the integral juncture hub or in a location that can be seen after the catheter has been inserted.</p>	Pass
<b>Clamp Closure Efficacy</b>	The clamp closure capability shall be such that when the clamps are in the fully constrained position, there shall be no flow through the lumen being tested when tested in accordance with BS EN ISO 10555-3 Annex A or JIS T 3218 Annex C.	Pass
<b>Flow restriction after clamping</b>	The extension lines shall not be permanently deformed from the use of extension line clamps during the maximum expected clamp duration of the catheter to the point where a restriction in the extension line decreases the gravity flow through the catheter below the minimum gravity flow rate requirement (i.e. 90 mL/hr)	Pass
<b><i>In vitro</i> efficacy testing – external antimicrobial treatment</b>	<p>The antimicrobial agent release rate will be sufficiently slow to provide efficacy against gram (+), gram (-) and fungi for a minimum of 7 days.</p> <p>Note: Efficacy will be based upon a minimum 4 log reduction of adherent biomass (microbial colonization) when compared to the initial inoculum concentration.</p>	Pass
<b><i>In vitro</i> efficacy testing – internal antimicrobial treatment</b>	<p>The antimicrobial agent release rate will be sufficiently slow to provide efficacy against gram (+), gram (-) and fungi for a minimum of 7 days.</p> <p>Note: Efficacy will be based upon a minimum 4 log reduction of adherent biomass (microbial colonization) when compared to the initial inoculum concentration.</p>	Pass
<b><i>In vivo</i> animal infection study</b>	The product shall exhibit efficacy against <i>Staphylococcus aureus</i> at minimum 7 days for <i>in-vivo</i> studies. Efficacy will be based upon a minimum 4 log reduction of adherent biomass (microbial colonization) when compared to the initial inoculum concentration.	Pass

## 9. Conclusions

The Arrow Antimicrobial Pressure Injectable PICCs are substantially equivalent to the Arrow Pressure Injectable PICCs (K061289) and the Arrow 6 French Triple Lumen Pressure Injectable PICCs (K080604). The subject devices have the same intended use, principles of operation and technological characteristics as the predicates. The indications for use, for the proposed catheters, are the same as the

Arrow PICC predicate device K080604 with the addition of the proposed catheter's effectiveness in reducing microbial colonization.

The antimicrobial agent for the proposed device is a similar Chlorhexidine-based solution used for the ARROW<sup>+</sup>ard Blue PLUS<sup>®</sup> Multi-Lumen CVC (K993691). The process of application of the antimicrobial agent is also similar to that of the predicate device.

The results of the testing performed have demonstrated that the Arrow Antimicrobial Pressure Injectable PICC devices are safe and perform as intended. The differences, between subject devices and predicate devices, do not raise any new issues of safety and effectiveness. Thus, the Arrow Antimicrobial Pressure Injectable PICCs are substantially equivalent to the predicate devices.



Food and Drug Administration  
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Silver Spring, MD 20993-0002

Ms. Tracy Maddock  
Regulatory Affairs Specialist  
Arrow International, Incorporated  
2400 Bernville Road  
Reading, Pennsylvania 19605

AUG 27 2010

Re: K100635

Trade/Device Name: Arrow Antimicrobial Pressure Injectable Peripherally  
Inserted Central Catheter (PICC)  
Regulation Number: 21 CFR 880.5970  
Regulation Name: Percutaneous, Implanted, Long-Term Intravascular Catheter  
Regulatory Class: II  
Product Code: LJS  
Dated: August 23, 2010  
Received: August 24, 2010

Dear Ms. Maddock:

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.

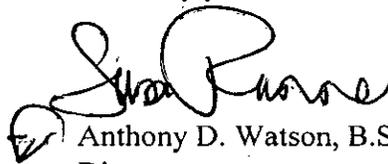
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 go to

<http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,



Anthony D. Watson, B.S., M.S., M.B.A.  
Director

Division of Anesthesiology, General Hospital,  
Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

K100635

**Indications for Use**

510(k) Number (if known): \_\_\_\_\_

Device Name: Arrow Antimicrobial Pressure Injectable Peripherally Inserted Central Catheter (PICC)

**Indications for Use:**

The Arrow Antimicrobial Pressure Injectable PICC 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 Arrow Antimicrobial Pressure Injectable PICC may not exceed 300 psi. Antimicrobial 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. Antimicrobial effectiveness was evaluated using *in vitro* methods, and no correlation between *in vitro* and clinical outcome has currently been ascertained. It is not intended to be used for the treatment of existing infections.

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)

Sara Papp

(Division Sign-Off)  
Division of Anesthesiology, General Hospital Page \_\_\_ of \_\_\_  
Infection Control, Dental Devices

510(k) Number: K100635