K112896

MAY 10 2012

ARROW INTERNATIONAL

510(k) SUMMARY

SUMMARY OF SAFETY AND EFFECTIVENESS
FOR
ARROWEVOLUTIONT!It PRESSURE INJECTABLE PICC
WITH CHLORAG+ARD ANTIMICROBIAL AND ANTITHROMBOGENIC TECHNOLOGY

1. Submitter Information

Name:	Arrow International, Inc (subsidiary ofTeleflex Inc.)
Address:	2400 Bernville Road Reading, PA 19605-9607
Telephone Number:	(610) 378-0131
Contact Person:	Tracy Maddock Regulatory Affairs Specialist
Telephone Number:	(610) 378-0131 Extension 3384
Fax Number:	(610) 374-5360
Email:	tracy.maddock@teleflex.com

Date Prepared: September 30, 2011

2. Device Narne

Device Trade Name:	AnowEVOLUTION™ Pressure Injectable PICC with Chlorag+ard Antimicrobial and Antithrombogenic Technology
Common Name:	Peripherally Inserted Central Catheter
Classification Name:	Percutaneous, implanted, long-term intravascular catheter (21 CFR 880.5970, Product Code LJS

3. Predicate Devices

Predicate 1: Arrow Antimicrobial Pressure Injectable PICC (K100635)
Predicate 2: PICC 4 Fr and 5 Fr Single and Dual Lumen (K083763)

4. Device Description

The ArrowEVOLUTIONTM Pressure Injectable PICC with Chlorag+ard Antimicrobial and Antithrombogenic Technology 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 em. The catheters can be used for the injection of contrast media. The maximum recommended infusion rate is 5 rnL/sec. The external catheter body and the internal fluid path of the device are treated with Chlorhexidine based solution technology. Studies have shown the technology to possess both antimicrobial and antithrombogenic properties.

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 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 An·owEVOLUTION™ 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.

6. Technological Characteristics and Substantial Equivalence

The ArrowEVOLUTION™ Pressure Injectable PICC with Chlorag+ard Antimicrobial and Antithrombogenic Technology is the same device as the Arrow Antimicrobial Pressure Injectable PICC cleared in K100635. The indications for use for the proposed catheter are the same with the addition of the proposed catheter's effectiveness in reducing thrombus accumulation on catheter surfaces. *In vitro* and *in vivo* testing support this added performance claims.

The ArrowEVOLUTION™ Pressure Injectable PICC with Chlorag+ard Antimicrobial and Antithrombogenic Technology is substantially equivalent to the PICC (K083763) in terms of intended use, principles of operation, and technological performance. The Zeus™ CT PICCs coating reduces the risk of thrombus adhering to the catheter. The coating on the Arrow EVOLUTION has also been shown to provide a reduction in thrombus accumulation and has been shown to be as safe and effective as the Zeus™ CT PICC in comparative *in vitro* and *in vivo* performance testing.

7. Nonclinical Testing

In vitro and *in vivo* testing was performed to assess the antithrombogenic effectiveness of the proposed device. Testing included *in vitro* thrombogenicity (platelet adhesion) and patency and *in vivo* animal studies comparing the proposed device and the predicate Zeus device. The ArrowEVOLUTION™ catheter performed as well as or better than the Zeus predicate device in both *in vivo* and *in vitro* testing making the proposed device substantially equivalent to the Zeus predicate in terms of technological performance.

8. Conclusions

The results of all testing performed on the ArrowEVOLUTION™ Pressure Injectable PICC with Chlorag+ard Antimicrobial and Antithrombogenic Technology device demonstrate that the proposed device is as safe, as effective, and performs as well as or better than the predicate devices. The proposed device is therefore substantially equivalent to the cited predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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

MAY 10 2012

Re: K112896
Trade/Device Name: ArrowEVOLUTION™Pressure Injectable PICC with Chlorag+ard Antimicrobial and Antithrombogenic Technology
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long-Term Intravascular Catheter
Regulatory Class: II
Product Code: LJS
Dated: April 26, 2012
Received: April 27, 2012

Dear Ms. Tracy 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,

for

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

Indications for Use

510(k) Number (ifkuown): K112896

Device Name: ArrowEVOLUTION™ Pressure Injectable PICC with Chlorag+ard Antimicrobial and Antithrombogenic Technology

Indications for Use:

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™ 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.

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 ofCDRH, Office of Device Evaluation (ODE)

5/10/12

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

510(k) Number: K112896