DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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September 12, 2016

Arrow International, Incorporated (Subsidiary of Teleflex, Incorporated)
Elizabeth Duncan
Senior Regulatory Affairs Specialist
2400 Bernville Road
Reading, Pennsylvania 19605

Re: K123759
Trade/Device Name: CG+ Arrow PICC Powdered by Arrow VPS Stylet
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long-Term Intravascular Catheter
Regulatory Class: Class II
Product Code: LJS, OBJ
Dated: December 6, 2012
Received: December 7, 2012

Dear Ms. Elizabeth Duncan:

This letter corrects our substantially equivalent letter of January 3, 2013.

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 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" (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 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,

Michael J. Ryan -S

for 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

Indications for Use

510(k) Number (if known): K123759

Device Name: **CG+ Arrow PICC powered by Arrow VPS Stylet**

Indications for Use:

The 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 injection equipment used with the pressure injectable PICC catheter 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 test methods and clinical outcome has currently been ascertained. It is not intended to be used for the treatment of existing infections or vein thrombosis.

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 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 P-wave. 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.

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Digitally signed by Richard C. Chapman
Date: 2013.01.04 14:46:32 -05'00'

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

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6 510(K) SUMMARY

Submitter Information

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Date Prepared:	December 6, 2012

Device Name

Device Trade Name: CG+ Arrow PICC powered by Arrow VPS Stylet
Common Name, Catheter: Peripherally Inserted Central Catheter (PICC)
Common Name, Stylet: Catheter, Ultrasound, Intravascular

Classification Name, Catheter: Percutaneous, implanted, long-term intravascular catheter per 21 CFR: 880.5970
Classification Name, Stylet: Diagnostic Intravascular Catheter per 21 CFR 870.1200

Predicate Devices

- K103255: Vascular Positioning System (VPS System) Stylet
- K112896: Pressure Injectable PICC with Chlorag+ard Antimicrobial and Antithrombogenic Technology

Device Description

The CG+ Arrow PICC powered by Arrow VPS Stylet has the following characteristics:

- 5.5 Fr, 2-Lumen, 40-55 cm pressure injectable, antimicrobial and antithrombogenic catheter preloaded with VPS Stylet

The CG+ Arrow PICC is pre-loaded with the Arrow VPS Stylet and will be provided in sterile kit configurations.

The Arrow CG+ 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 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 solution technology. Studies have shown the technology to possess both antimicrobial and antithrombogenic properties.

The Arrow VPS Stylet is a polyimide tube containing a Doppler sensor on a coax cable and an intravascular electrocardiogram (ivECG) signal sensing stainless steel wire. The Doppler sensor and the exposed portion of the ivECG are located at the distal end of the stylet and are used to detect and transmit physiological information to the VPS Console for analysis. The proximal end contains a connector to the VPS Console or to an extension cable that in turn connects to the VPS Console. The stylet was designed to be able to be inserted and removed from any catheter with a luminal diameter of at least 0.021 inch.

For user convenience, Arrow has created the CG+ Arrow PICC powered by Arrow VPS Stylet in which the Arrow Pressure Injectable PICC with Chlorag+ard Antimicrobial and Antithrombogenic Technology is provided pre-loaded with the Arrow VPS Stylet. To accommodate the VPS stylet, the internal lumen configuration of the predicate Arrow Pressure Injectable PICC with Chlorag+ard Antimicrobial and Antithrombogenic Technology (K112896) has changed from a "Double-D" design to a "Round-Crescent". As a result of the internal lumen design change, the flow rate of the proximal lumen has changed from a maximum rate of 5 ml/sec to 4 ml/sec. The distal lumen flow rate remains the same as the predicate PICC (K112896).

Intended Use

A PICC permits venous access to the central circulation through a peripheral vein.

The intended use of the VPS Stylet and Console (VPS System) is to quickly and accurately guide market available central catheters to the desired location which is the lower third of the SVC or at the cavo-atrial junction.

Technological Characteristics and Substantial Equivalence

The CG+ Arrow PICC powered by Arrow VPS Stylet is substantially equivalent to the Vascular Positioning System (VPS System) Stylet (K103255) in terms of indications for use, design, manufacturing process, conditions and aids, functional performance, safety, efficacy and materials of construction. The CG+ Arrow PICC powered by Arrow VPS Stylet is substantially equivalent to the Pressure Injectable Peripherally Inserted Central Catheter (PICC) with Chlorag+ard Antimicrobial and Antithrombogenic Technology (K112896) in terms of indications for use, manufacturing process, conditions and aids, safety, efficacy and materials of construction. To accommodate the VPS stylet, the internal lumen configuration of the predicate Arrow Pressure Injectable PICC with Chlorag+ard Antimicrobial and Antithrombogenic Technology (K112896) has changed from a "Double-D" design to a "Round-Crescent". The antimicrobial / antithrombogenic chlorhexidine solution remains unchanged. As a result of the internal lumen design change, the maximum pressure injection flow rate of the proximal lumen has been reduced from a 5 ml/sec to 4 ml/sec. The maximum pressure injectable flow rate of the distal lumen flow rate remains the same as the predicate PICC (K112896) at 5 ml/sec.

No changes were made to the chlorhexidine solution as a result of this change. The solution's specifications (formulation), total content, content per surface area, manufacturing processes, conditions and aids as well as the process by which the catheter is treated remain unchanged from the predicate PICC (K112896).

No changes were made to the proposed Stylet.

The subject device combines the predicate Arrow VPS Stylet and the Arrow Pressure Injectable PICC with Chlorag+ard Antimicrobial and Antithrombogenic Technology; there is no change to the indications for use.

Nonclinical Testing

The following testing was performed on the CG+ Arrow PICC powered by Arrow VPS Stylet:

Chlorhexidine solution testing: chlorhexidine content testing, chlorhexidine solution efficacy, chlorhexidine release rate (elution), solvent residual and chemical degradation.

Catheter performance testing: tensile, catheter body kink, flow rate, static burst pressure, air and liquid leakage, flex cycling, catheter whip, catheter tip compression stiffness, collapse resistance and CVP monitoring.

Combined device performance testing: stylet tensile, simulated use insertion/removal test and force to remove stylet from catheter. After devices completed the simulated use insertion/removal test, the following tests were done to verify there was no damage to the catheter: catheter air and liquid leakage and stylet electrical testing.

Conclusions

The predicate and the subject devices have the same indications for use, intended use, materials, chlorhexidine specifications and content and are manufactured using the same processes, conditions and aids. The results of the testing performed have demonstrated that combining the two previously cleared devices and changing the internal lumen configuration of the catheter to accommodate the VPS stylet do not raise new issues of safety or effectiveness and therefore the combination and design change is considered substantially equivalent to the cited predicate devices.