6 **510(K) SUMMARY** K141618

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Submitter Information

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Date Prepared:	June 16, 2014

Device Name

Device Trade Name: Arrow VPS Stylet *PLUS* and CG+ Arrow PICC powered by Arrow VPS Stylet *PLUS*
Common Name, Stylet: Catheter, Ultrasound, Intravascular
Classification Name, Stylet: Diagnostic Intravascular Catheter per 21 CFR 870.1200

Predicate Devices

- K103255: Vascular Positioning System (VPS) Stylet
- K122545: 4.5 French CG+ Arrow PICC powered by Arrow VPS Stylet
- K123759: 5.5 French CG+ Arrow PICC powered by Arrow VPS Stylet
- K130876: 6 French CG+ Arrow PICC powered by Arrow VPS Stylet

Device Description

The Arrow Vascular Positioning System (VPS) Stylet *PLUS* (hereafter referred to as Arrow VPS Stylet *PLUS*) is designed for use with a VPS Console to guide market available central catheters to the desired location, which is the lower third of the superior vena cava (SVC) or at the cavo-atrial junction. The CG+ Arrow PICC powered by Arrow VPS Stylet *PLUS* provides the user with an Arrow VPS Stylet *PLUS* already loaded into a central catheter. (The Arrow VPS Stylet *Plus* and the Arrow VPS Stylet *Plus* included in the CG+ Arrow PICC powered by Arrow VPS Stylet *Plus* are exactly the same stylet.)

The subject device, the Arrow VPS Stylet *PLUS* has the following characteristics:

- 6 ft overall length
- ≤ 0.021" outer diameter over working length of polyimide with polytetrafluoroethylene (PTFE) heat shrink
- Intravascular electrocardiogram (ivECG) signal sensing stainless steel wire with exposed portion at the distal end
- Doppler transducer connected to coaxial cable at the distal end
- Coaxial cable and ivECG wire attached to connector at the proximal end to be plugged in to VPS Console or extension cable (that in turn connects to the VPS Console)
- Tuohy-Borst adapter
- Marking accessory

The Arrow VPS Stylet *PLUS* is the stylet portion of a vascular positioning system designed to be used with the VPS Console and a market-available catheter. The Arrow VPS Stylet *PLUS* is a polyimide tube with a fluoropolymer (PTFE) heat shrink. The tubing contains a Doppler sensor on a coaxial 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 CG+ Arrow PICC Powered by Arrow VPS Stylet *PLUS* is the Arrow VPS Stylet *PLUS* preloaded into a 4.5 Fr 1-Lumen, 5.5 Fr 2-Lumen, and 6 Fr 3-Lumen, 40-55 cm pressure injectable antimicrobial and antithrombogenic Peripherally Inserted Central Catheter (PICC).

The CG+ Arrow 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 external catheter body and the internal fluid path of the device are treated with Chlorag+ard, a Chlorhexidine-based coating technology.

Intended Use

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

The CG+ Arrow PIC Catheters powered by Arrow VPS Stylet *PLUS* permit venous access to the central circulation through a peripheral vein, with the guidance of the VPS system.

Technological Characteristics and Substantial Equivalence

Characteristic	Predicate Device	Subject Device
Design	6 foot long stylet which contains a Doppler sensor and an intravascular electrocardiogram (ivECG) signal sensing wire at the distal tip	**SAME:** 6 foot long stylet which contains a Doppler sensor and an intravascular electrocardiogram (ivECG) signal sensing wire at the distal tip
Signal Conductor	Two conductor stylet wires (ECG wire and coaxial cable)	**SAME:** Two conductor stylet wires (ECG wire and coaxial cable)
ECG Conductor pathway	Exposed conductive surface at distal end of ECG wire	**SAME:** Exposed conductive surface at distal end of ECG wire
Connector	Single, 7 prong custom	**SAME:** Single, 7 prong custom
Polyimide Tube OD and ID (nominal)	OD: 0.0180" ID: 0.0150"	OD: 0.0154" ID: 0.0134"
Coaxial cable OD (nominal)	OD: .0073"	OD: .0063"
Stylet Materials	**Transducer wire sleeve (stylet body):** Polyimide embedded with Fluoropolymer (PTFE)	**Transducer wire sleeve (stylet body):** Polyimide with Fluoropolymer (PTFE) heat shrink
	Tuohy-Borst: Polycarbonate, Polypropylene, silicone	**Tuohy-Borst:** Polycarbonate, Polypropylene, PTFE, TPE
	Coaxial cable: Encapsulated Silver Plated Copper Wire	**Coaxial cable: SAME,** Encapsulated Silver Plated Copper Wire
	Epoxy: Silver-filled Epoxy	**Epoxy: SAME,** Silver-filled Epoxy
	Stylet jacket: Gray Santoprene, 60-68 shore A (durometer)	**Stylet jacket:** Black Santoprene, 55 shore A (durometer)
Stylet Doppler Transducer Operating Frequency	11.667 MHz	**SAME:** 11.667 MHz
Stylet Doppler Transducer Size	0.5 mm	0.4 mm
Stylet Doppler Transducer Shape	Cruciform	Hexagonal
Marking Accessory	Ink marker	Twist-locking collet
PIC Catheters	All characteristics: materials, diameter, lengths, manufacturing processes, conditions and aids	**SAME:** All characteristics
Chlorhexidine Technology	All characteristics: Identity, formulation, concentration (content per surface area), manufacturing processes, conditions and aids, method of application to the device and mechanism by which the agent is released from the device	**SAME:** All characteristics
Stylet Shelf life	2 years	1 year
Sterilization: All characteristics, including: method, assurance level	**All characteristics, including:** **Method:** Ethylene Oxide **Assurance Level:** 10^{-6}	**SAME:** All characteristics, including: **Method:** Ethylene Oxide **Assurance Level:** 10^{-6}
Packaging	**Standalone kits:** PETG tray sealed in a Tyvek header pouch **Preloaded kits:** PETG tray with a Tyvek lidstock	**SAME:** **Standalone kits:** PETG tray sealed in a Tyvek header pouch **Preloaded kits:** PETG tray with a Tyvek lidstock

The Arrow VPS Stylet *PLUS* and CG+ Arrow PICC powered by Arrow VPS Stylet *PLUS* is substantially equivalent to the predicate VPS Stylet (K103255) and the CG+ Arrow PICC powered by Arrow VPS Stylet (K122545, K123759, K130876) in terms of intended use, indications for use, patient population, contraindications, operating principle, functional performance, safety, efficacy, sterilization, fundamental scientific technology, material and design. Any differences between the subject device and the predicates do not render the device not-substantially equivalent (NSE), affect safety or effectiveness, or raise different questions of safety and effectiveness as proven through passing verification results.

There are **no changes** to the catheter or Chlorag+ard Technology portion of the predicate Arrow CG+ PICC catheters preloaded with the VPS Stylet (K122545, K123759, K130876). There are **no changes** being made to the VPS Consoles (K103260 and K123813), as part of this submission.

Nonclinical Testing

The following testing was performed on the Arrow VPS Stylet *PLUS* and the CG+ Arrow PICC powered by Arrow VPS Stylet *PLUS* after being preconditioned with EtO sterilization, ISTA simulated environmental conditions and one year accelerated aging:

Test Device	Test	Results
Stylet	Tensile	PASS
	Torque strength	PASS
	Tip Flexibility	PASS
	Flexing BS EN ISO 11070	PASS
	Fracture BS EN ISO 11070	PASS
	Corrosion BS EN ISO 11070	PASS
	Component Compatibility: Marking accessory grip strength	PASS
	Component Compatibility: Tuohy-Borst Adapter grip strength	PASS
	Tuohy-Borst Leak	PASS
	Physical characteristics	PASS
	X-ray Detectability ASTM F640-07	PASS
	Electrical Performance: Hi-Pot, Continuity, Doppler Bandwidth, Capicitance, Sensitivity, Sensitivity stability	PASS
	Biocompatibility: Cytotoxicity, Irritation, Sensitization, Acute Systemic Toxicity and Hemocompatibility per ISO 10993-1	PASS
Combined device	Electrical Safety and Electromagnetic Compatibility Testing (IEC 60601-1-2, IEC 60601-2-37)	PASS
	Catheter Compatibility Simulated Use Insertion/ Removal	PASS
	Catheter Compatibility Force to Remove stylet from catheter	PASS

Conclusions

The subject device is substantially equivalent to the predicate device in terms of intended use, indications for use, patient population, contraindications, operating principle, functional performance, safety, efficacy, fundamental scientific technology, design and material. The results of the risk assessment and resultant testing performed have demonstrated that the design and material modifications do not raise new issues of safety or effectiveness and therefore the subject device is considered substantially equivalent to the cited predicate device, performs as well as and is as safe and effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

July 8, 2014

Arrow International, Inc. (subsidiary Of Teleflex Inc.)
Elizabeth Duncan
Senor Regulatory Affairs Specialist
2400 Bernville Road
Reading, PA 19605-907 USA

Re: K141618
Trade/Device Name: Arrow VPS stylet *PLUS* and CG+ Arrow PICC powered by ArrowVPS Stylet *PLUS*
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic intravascular catheter
Regulatory Class: II
Product Code: OBJ
Dated: June 16, 2014
Received: June 17, 2014

Dear Ms. Duncan:

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" (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 yours,

Mary S. Runner -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
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Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K141618

Device Name: **Arrow VPS Stylet *PLUS***

Indications for Use:

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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Indications for Use

510(k) Number (if known): K141618

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

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.

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