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

February 4, 2016

Arrow International, Inc. (subsidiary of Teleflex Inc.)
Elizabeth Duncan
Sr. Regulatory Affairs Specialist
2400 Bernville Road
Reading, PA 19605

Re: K153487
Trade/Device Name: CG+ Arrow PICC powered by Arrow VPS Stylet *PLUS* and Arrow VPS Stylet *PLUS*
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long-Term Intravascular Catheter
Regulatory Class: II
Product Code: LJS, OBJ
Dated: January 6, 2016
Received: January 7, 2016

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,

for Erin I. Keith, M.S.
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)*
K153487

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

Indications for Use *(Describe)*
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 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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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)*
K153487

Device Name
Arrow VPS Stylet PLUS

Indications for Use *(Describe)*
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.

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K153487

510(K) SUMMARY *PER 21 CFR 807.92*

Submitter Information

Name:	Arrow International, Inc (subsidiary of Teleflex Inc.)
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Contact Person:	Elizabeth Duncan Sr. Regulatory Affairs Specialist
Telephone Number:	(610) 378-0131 Extension 603220
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Date Prepared:	December 3, 2015

Device Name

Device Trade Name: CG+ Arrow PICC powered by Arrow VPS Stylet *PLUS* and Arrow VPS Stylet *PLUS*
Device Common Name:
Catheter: Peripherally Inserted Central Catheter
Stylet: Catheter, Ultrasound, Intravascular
Device Classification Name:
Catheter**:** Percutaneous Implanted Long-Term Intravascular Catheter
Stylet: Diagnostic Intravascular Catheter
FDA Classification Regulation:
Catheter: 21 CFR: 880.5970
FDA Classification (Catheter and Stylet)**:** Class II
FDA Product Code:
Catheter: LJS
Stylet: OBJ

Predicate Devices

- K141618: Arrow Vascular Positioning System (VPS) stylet *PLUS* and CG+ Arrow PICC powered by Arrow VPS Stylet *PLUS*

Modifications

This Special 510(k) is being submitted for design and material modifications to the predicate Arrow VPS Stylet *PLUS* and the Arrow VPS Stylet *PLUS* included in the predicate CG+ Arrow PICC powered by Arrow VPS Stylet *PLUS* (K141618). The following is a list of modifications being made to the subject device followed by the reasons for the changes:

Material modification

- Addition of a platinum-iridium conductor band assembly and associated adhesive

Design Modification

- Increase in stylet body inner diameter (ID); decrease in outer diameter (OD)
- Increase in the ECG wire body OD
- Decrease in the co-ax wire OD
- Connector design changes
- Process of PTFE coating

See the "Technological Characteristics and Substantial Equivalence" table below for more detailed information.

The predicate premarket notification for the Arrow VPS Stylet *PLUS* and the Arrow VPS Stylet *PLUS* included in the predicate CG+ Arrow PICC powered by Arrow VPS Stylet *PLUS* (K141618) did not contain information about the VPS Console; Console information was contained within separate cleared 510(k)s (K103260 and K123813). There are **no changes** to the VPS Consoles associated with this submission.

There are **no changes** to the catheter or Chlorag+ard technology portion of the predicate Arrow CG+ Arrow PICC powered by the Arrow VPS Stylet (K141618).

Device Description

The purpose of this premarket notification is to propose design and material modifications to the subject device: the Arrow Vascular Positioning System (VPS) stylet *PLUS* and CG+ Arrow PICC powered by Arrow VPS Stylet *PLUS* . 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)
- Intravascular electrocardiogram (ivECG) signal sensing conductor consists of a platinum-iridium (Pt/Ir) conductor band assembly
- 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 for use in a hospital setting by trained clinicians. 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* body is a polyimide tube with a fluoropolymer (PTFE) coating. The tubing contains a Doppler sensor on a coaxial cable and an intravascular electrocardiogram (ivECG) signal sensing platinum-iridium (Pt/Ir) conductor band with an intermediate stainless steel cannula that is welded to the stainless steel ECG wire. The stainless steel portions of the ECG conductor are encased within the platinum-iridium band. The Doppler sensor and the only exposed portion of the ivECG, i.e. the platinum-iridium band, 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 be plugged into 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, 40-55 cm pressure injectable Chlorag+ard 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 subject and predicate (K141618) devices are identical and are listed below.

The intended use of the Arrow VPS Stylet *PLUS* and VPS Console (together with 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.

Indications for Use

The indications for use of the subject and predicate (K141618) devices are identical and are listed below.

Arrow VPS Stylet *PLUS*:

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.

CG+ Arrow PIC Catheters powered by Arrow VPS Stylet *PLUS*:

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 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.

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
ECG wire OD (nominal)	.006"	.007"
Connector	Single, 7 prong custom, 2 barbs	Single, 7 prong custom, with the addition of a barb, two clips and grooves
Stylet body OD and ID (nominal)	ID: 0.0134" OD: 0.0187"	ID: 0.0144" OD: 0.0174"
Coaxial cable OD (nominal)	OD: .0063"	OD: .0062"
Stylet Patient Contacting Materials (Circulating Blood contact for limited duration)	**Stylet body:** Polyimide with Fluoropolymer (PTFE) heat shrink	**Stylet body: SAME material, different process,** Polyimide coated with Fluoropolymer (PTFE)
	ECG Conductor: 304V SST	**ECG Conductor:** Platinum-Iridium band welded to 304V SST
	Tuohy-Borst: Polycarbonate, Polypropylene, silicone, PTFE, TPE	**Tuohy-Borst: SAME**, Polycarbonate, Polypropylene, silicone, PTFE, TPE
	Adhesive encased over transducer: Loctite 3311 UV Cured Acrylic	**SAME:** Loctite 3311 UV Cured Acrylic
	Adhesive used to bond ECG assembly to stylet body: Loctite 3311 UV cured acrylic	**Adhesive used to bond ECG assembly to stylet body:** Loctite 4014 Cyanoacrylate acrylic adhesive
Operating Frequency of Stylet Doppler Transducer	11.667 MHz	**SAME:** 11.667 MHz
Size of Stylet Doppler Transducer	0.4 mm	**SAME:** 0.4 mm
Stylet Doppler Transducer Shape	Hexagonal	**SAME:** Hexagonal
Marking Accessory	Twist-locking collet	**SAME:** Twist-locking collet
PIC Catheters	All characteristics: materials, diameter (4.5, 5.5, 6 Fr.), lengths, manufacturing processes, conditions and aids	**SAME:** All characteristics: materials, diameter (excluding the 6 Fr, since this sized catheter is not included in the subject device), lengths, manufacturing processes, conditions and aids
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

Characteristic	Predicate Device	Subject Device
Instruction s for Use	Content	**Stylet: SAME** **Catheter: SAME**
Stylet Shelf life	1 year	**SAME:** 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:** PET tray sealed in a Tyvek header pouch **Preloaded kits:** PETG tray with a Tyvek lidstock	**Standalone kits:** Polystyrene (HIPS) tray with Tyvek sterile barrier **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 Arrow VPS Stylet *PLUS* and the CG+ Arrow PICC powered by Arrow VPS Stylet *PLUS* (K141618) in terms of: intended use, indications for use, patient population, contraindications, operating principle, functional performance, sterilization, fundamental scientific technology, features, material and design.

There are **no changes** to the catheter or Chlorag+ard Technology portion of the predicate CG+ Arrow PICC catheters powered by Arrow VPS Stylet *PLUS* (K141618). There are **no changes** being made to the VPS Consoles (K103260 and K123813), as part of this submission.

Nonclinical Testing

The modifications proposed to the subject device were evaluated using risk management. The risk analysis method used to assess the impact of the modifications was per ISO 14971 and included a Risk Management Plan, Hazards Analysis, and Risk Management Report. As a result of the risk assessment, the testing listed in the table below was determined to be required. The resultant testing listed in the table below was performed on the subject device: 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 per ISO 10555-1	PASS
	Torque strength Per the Coronary and Cerebrovascular Guidewire guidance	PASS
	Tip Flexibility Per the Coronary and Cerebrovascular Guidewire guidance	PASS
	Flexing BS EN ISO 11070	PASS
	Corrosion BS EN ISO 10555-1	PASS
	Component Compatibility: Marking accessory grip strength	PASS
	Component Compatibility: Tuohy-Borst Adapter grip strength	PASS
	Tuohy-Borst Leak per 594-1	PASS
	Physical characteristics	PASS
	X-ray Detectability ASTM F640-07	PASS
	Electrical Performance: Hi-Pot, Continuity, Doppler Bandwidth, Capacitance, Sensitivity stability	PASS
	Biocompatibility: Cytotoxicity, Irritation, Sensitization, Acute Systemic	PASS

Test Device	Test	Results
	Toxicity and Hemocompatibility per ISO 10993-1	
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, fundamental scientific technology, features, design and material. The results of the risk assessment and resultant testing performed have demonstrated that the design and material modifications is as safe, as effective and performs as well as the predicate device and therefore the subject device is considered substantially equivalent to the cited predicate device.