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

June 5, 2015

Arrow International (a Subsdiary of Teleflex, Inc.)
Mr. Karl Nittinger
Senior Regulatory Affairs Specialist
2400 Bernville Rd.
Reading, Pennsylvania 19605

Re: K150109
Trade/Device Name: Arrow Pressure Injectable Jugular Axillo-subclavian Central Catheter (JACC) with Sustain Technology
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: FOZ
Dated: May 1, 2015
Received: May 4, 2015

Dear Mr. Nittinger:

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" (21 CFR 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,

Tina Kiang -S

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

SECTION 5. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K150109

Device Name: Arrow Pressure Injectable Jugular Axillo-subclavian Central Catheter (JACC) with Sustain Technology

Indications for Use:

The Arrow Pressure Injectable Jugular Axillo-subclavian Central Catheter (JACC) with Sustain Technology is indicated for short-term (up to 30-days) access to the central venous system for intravenous therapy, infusion, pressure injection of contrast media, and allows for central venous pressure monitoring. The maximum pressure of power injector equipment used with the Arrow Pressure Injectable JACC with Sustain Technology may not exceed 300 PSI. The maximum pressure injection flow rate for the specific lumen being used for pressure injection is printed on the extension line hub.

Prescription Use X	AND/OR	Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D)		(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)

SECTION 6. 510(k) SUMMARY
Arrow Pressure Injectable Jugular Axillo-subclavian Central Catheter (JACC) with Sustain Technology
Submission Number: K150109

1. Applicant Information**:**

Arrow International (a subsidiary of Teleflex, Inc.)
2400 Bernville Rd.
Reading, PA 19607

Contact Person: Karl J. Nittinger
Telephone Number: (610) 378-0131, ext. 603384
Fax Number: (610) 478-3179

Date Prepared: 5-June-2015

2. Device Name:

- Proprietary Name: Arrow Pressure Injectable Jugular Axillo-subclavian Central Catheter (JACC) with Sustain Technology
- Classification Name: Intravascular catheter
- CFR Number: 21 CFR 880.5200
- Device Class: II
- Product Code: FOZ (Catheter, Intravascular, Short-Term Less Than 30 Days).

3. Predicate and Reference Device(s):

Predicate Device Name	510(k)	Original Applicant Name
Pressure Injectable JACC with Chlorag+ard Antimicrobial and Antithrombogenic Technology.	K132133	Arrow International
Arrow, Arrowg+ard and Arrowg+ard Blue Plus Pressure-Injectable Central Venous Catheters	K071538	Arrow International
NMI PICC IV (BioFlo PICC with Endexo Technology)	K140266	Navilyst Medical
6 Fr, 3-Lumen Pressure Injectable PICC	K080604	Arrow International

Reference Device Name	510(k)	Original Applicant Name
Nylus™ PICC	K113225	Semprus Biosciences

4. Description of Device:

The Arrow Pressure Injectable Jugular Axillo-subclavian Central Catheter (JACC) with Sustain Technology is a single-use catheter intended for percutaneous insertion over a guidewire to facilitate access to the central venous system. The device is intended for short term use (up to 30 days) and is provided sterile in a convenience kit configuration which includes single-use accessories to facilitate the insertion procedure. These accessories may include, but are not limited to; introducer needles, guidewires, tissue dilators, and catheter securement devices.

The Arrow Pressure Injectable JACC with Sustain Technology features a radiopaque polyurethane catheter body with a soft, tapered distal tip. The device design is summarized as follows:

- Catheter Body OD: 6 French
- Lumens: 3
- Catheter Body Length: 20 cm

The proximal end of the catheter includes extension lines with integral Luer hubs to facilitate access to the catheter body lumens for infusion and aspiration. The distal lumen of the Arrow Pressure Injectable JACC with Sustain Technology is compatible with power injection flow rates up to 6 ml /sec and pressures up to 300 PSI.

The full-length of the outer surface (and partial length of the internal lumen surface) of the Arrow Pressure Injectable JACC with Sustain Technology is modified with a biomimetic polymer technology. The "Sustain" polymer surface modification technology is intended to reduce platelet adhesion and thrombus accumulation.

5. Indications for Use:

The Arrow Pressure Injectable Jugular Axillo-subclavian Central Catheter (JACC) with Sustain Technology is indicated for short-term (up to 30 days) access to the central venous system for intravenous therapy, infusion, pressure injection of contrast media, and allows for central venous pressure monitoring. The maximum pressure of power injector equipment used with the Arrow Pressure Injectable JACC with Sustain Technology may not exceed 300 PSI. The maximum flow rate for the specific lumen being used for pressure injection is printed on the extension line hub.

6. Substantial Equivalence

Intended Use / Indications for Use:

The subject Arrow Pressure-Injectable JACC with Sustain Technology has the same intended use as the predicate devices. The subject and predicate devices are intended to provide access to the central venous system.

The indications for use of the subject device are similar to those of the predicate devices in that all are indicated to provide intravenous therapy including: infusion, pressure injection of contrast media, and central venous pressure monitoring. While the subject device is intended for short-term (up to 30-days) use only, the predicate and reference devices also include indications for long-term use.

Technological Characteristics:

The subject Arrow Pressure-Injectable JACC with Sustain Technology (Arrow Sustain JACC) and the predicate devices are all catheters of radiopaque polyurethane construction. All of the devices include multi-lumen design configurations (the subject device features a 3-lumen design only) and all are offered in outer diameter range of 3 Fr – 6 Fr (the subject device is offered in 6 Fr only). Both the subject Arrow Sustain JACC and the predicate: Arrow Chlora+gard JACC (K132133), Pressure-Injectable PICC (K080604), and Pressure Injectable CVC (K071538) feature tapered, flexible distal tips and all of the devices are pressure injectable with pressure injection flow ratings within the range of 4 ml/sec to 6 ml/sec.

The subject Arrow Sustain JACC as well as the predicate Arrow Pressure-Injectable JACC with Chlorag+ard Technology (K132133), the predicate Nylus PICC (K113225), and the predicate BioFlo PICC (K140266) are offered with antithrombogenic design features. While the predicate Arrow Chlora+gard JACC (K132133) incorporates an antimicrobial / antithrombogenic chlorhexidine-based coating technology, the subject device and the reference Nylus™ PICC (K113225) device incorporate the same “Sustain” biomimetic polymer surface modification to facilitate thromboresistant properties. The predicate BioFlo PICC (K140266) incorporates the Endexo™ technology to achieve its antithrombogenic properties.

Proposed Device Arrow Pressure-Injectable JACC with Sustain Technology	**Predicate Device** Arrow Pressure-Injectable JACC with Chlorag+ard Antimicrobial and Antithrombogenic Technology (K132133)	**Predicate Device** Arrow, Arrowg+ard, Arrowg+ard Blue Plus Pressure-Injectable Central Venous Catheters (K071538)	**Predicate Device** Arrow Pressure-Injectable PICC (K080604)	**Predicate Device** NMI PICC IV (BioFlo PICC with Endexo Technology) (K140266)	**Reference Device** Nylus™ PICC (K113225)
Indications for Use: The Arrow Pressure Injectable Jugular Axillo-subclavian Central Catheter (JACC) with Sustain Technology is indicated for short-term (up to 30 days) access to the central venous system for intravenous therapy, infusion, pressure injection of contrast media, and allows for central venous pressure monitoring. The maximum pressure of power injector equipment used with the Arrow Pressure Injectable JACC with Sustain Technology may not exceed 300 PSI. The maximum flow rate for the specific lumen being used for pressure injection is printed on the extension line hub.	**Indications for Use:** The Arrow Pressure Injectable Jugular Axillo-subclavian Central Catheter (JACC) with Chlorag+ard Antimicrobial and Antithrombogenic Technology is indicated for short-term or long-term 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 power injector equipment used with the Arrow Pressure Injectable JACC with Chlorag+ard Antimicrobial and Antithrombogenic Technology may not exceed 300 PSI. The maximum flow rate for the specific lumen being used for pressure injection is printed on the extension line hub.	**Indications for Use:** The Arrow, Arrowg+ard, and Arrowg+ard Blue Plus catheters are indicated to permit short-term (< 30 days) access for the treatment of diseases or conditions requiring central venous access including; replacement of multiple peripheral sites for IV access; lack of peripheral IV sites; central venous pressure monitoring; TPN; infusion of incompatible medications; multiple infusions of fluids, medications, or chemotherapy; frequent blood sampling or receiving blood transfusions/blood products; infusions that are hypertonic, hyperosmolar, or infusions that have divergent pH; injection of contrast media. When used for pressure injection of contrast media, do not exceed the maximum	**Indications for Use:** The Arrow 6 Fr, Triple-Lumen, Pressure-Injectable Peripherally Inserted Central Catheter is indicated for short-term or long-term peripheral access to the central venous system for intravenous therapy, blood sampling, infusion, power injection of contrast media, and allows for central venous pressure monitoring. The maximum of power injector equipment used with the pressure injectable PICC may not exceed 300 PSI.	**Indications for Use:** The NMI PICC IV is indicated for short-or long-term peripheral access to the central venous system for intravenous therapy, including, but not limited to, the administration of fluids, medications and nutrients, the sampling of blood, for central venous pressure monitoring and for power injection of contrast media.	**Indications for Use:** The Nylus™ PICC is intended to provide peripheral access to the central venous system for infusion, intravenous therapy, blood sampling, central venous pressure monitoring, and power injection of contrast media. The Nylus PICC is indicated for dwell times shorter or greater than 30days. The device has a recommended infusion rating of 5ml/sec.

Proposed Device Arrow Pressure-Injectable JACC with Sustain Technology	**Predicate Device** Arrow Pressure-Injectable JACC with Chlorag+ard Antimicrobial and Antithrombogenic Technology (K132133)	**Predicate Device** Arrow, Arrowg+ard, Arrowg+ard Blue Plus Pressure-Injectable Central Venous Catheters (K071538)	**Predicate Device** Arrow Pressure-Injectable PICC (K080604)	**Predicate Device** NMI PICC IV (BioFlo PICC with Endexo Technology) (K140266)	**Reference Device** Nylus™ PICC (K113225)
Catheter Length					
20 cm	15 – 35 cm	16 cm - 20	40 cm – 55 cm	55 cm	60 cm
Catheter Outer Diameter (Ga. and French)					
6	4.5, 5.5, and 6	16 Ga., 7 Fr – 8.5 Fr	6	3, 4, 5, and 6	5
Number of Lumens					
3	1, 2, and 3	1, 2, 3, and 4	3	1, 2, and 3	2
Pressure Injection Capability					
Distal lumen only (6 ml/sec)	1-lumen catheter: Distal lumen only (5 ml/sec) 2-lumen catheter: Distal lumen (5 ml/sec) Proximal lumen (4 ml/sec) 3-lumen catheter: Distal lumen only (6ml/sec)	5 ml/sec – 10 ml/sec max. flow rates for pressure injectable lumens.	Distal-lumen only (6ml/sec) .	6 ml/sec max. flow rate.	Both lumens (5ml/sec)
Catheter Body Materials					
Radiopaque Polyurethane	Radiopaque Polyurethane	Radiopaque polyurethane.	Radiopaque Polyurethane	Radiopaque Polyurethane	Radiopaque Polyurethane
Distal Tip					
Tapered, flexible tip.	Tapered, flexible tip.	Tapered, flexible tip.	Tapered, flexible tip.	Straight, blunt tip.	Straight, blunt tip.
Catheter Surface Treatment					
"Sustain" biomimetic polymer surface modification with platelet adhesion-resistant and thrombus accumulation-resistant properties.	Chlorhexidine-based coating with antimicrobial as well as platelet adhesion and thrombus accumulation resistant properties.	Arrow CVC: None Arrowg+ard and Arrowg+ard Blue Plus CVC: Chlorhexidine-based antimicrobial coating.	None	"Endexo" polymer additive with platelet adhesion-resistant and thrombus accumulation-resistant properties.	"Sustain" biomimetic polymer surface modification with platelet adhesion-resistant and thrombus accumulation-resistant properties.
Sterility: All devices provided sterile. Sterilized by ethylene oxide.					

7. Non-Clinical Performance Data.

Bench testing verifying the performance requirements of the subject Arrow Pressure-Injectable JACC with Sustain Technology (Sustain JACC) was conducted and the results support substantial equivalence.

Testing included:

- BS EN ISO 10555-1 and BS EN ISO 10555-3: *Force at Break, Elongation, Flow Rate, Liquid Leakage, Air Leakage*
- BS EN 20594-1 and BS EN 1707: *Gauging, Liquid Leakage, Air Leakage, Separation Force, Stress Cracking, Unscrewing Torque, Ease of Assembly, Resistance to Overriding.*
- Additional Performance Verification Testing: *Repeat Pressure Injection, Static Burst, Flow Rate Under Pressure Injection, Flex Cycling, Compression Stiffness, Collapse Resistance, Kink Resistance, Pressure Monitoring, Site Care Chemical Exposure, Mechanical Hemolysis, Extension Line Clamp Functionality, Radio-detectability*
- Biocompatibility: According to the requirements identified in ISO 10993-1 for externally communicating devices with circulating blood contact for up to a 30-day duration, the following tests were performed: *Cytotoxicity, Irritation, Sensitization, Acute Systemic Toxicity, Subacute Toxicity, Genotoxicity, Implantation (4-week), Hemocompatibility*. In addition, a study characterizing any leachable and extractable chemical components associated with the subject device was included.

The Sustain JACC features a polymer surface modification which is designed to provide thromboresistant properties to the catheter surface. *In vitro* assessment has shown that the external Sustain JACC catheter surface was more resistant to platelet adhesion than the external surface of an untreated catheter. No correlation of *in vitro* results to clinical performance has been ascertained.

***in vitro* Performance Characteristic**	***in vitro* Performance Result**
Platelet Adhesion on External Catheter Surface	A paired analysis of *in vitro* measurements of adhesion of radio-labeled platelets to the external catheter surface of the Sustain JACC demonstrated an average reduction of 87% when compared to platelet adhesion measurements on the external surface of an untreated polyurethane catheter.[1]

[1]*In vitro* testing was conducted in a 1-2 hour flow loop utilizing bovine blood. No correlation of *in vitro* results to clinical performance has been ascertained. *In vivo* testing of the Sustain JACC in an ovine model demonstrated statistically equivalent performance with respect to in-life catheter patency, post-mortem catheter and vessel patency, post-mortem device thrombus, and post-mortem thrombus weight in comparison to an untreated control catheter and a control catheter featuring thromboresistant technology.

Animal Testing:

Data from an *in vivo* study assessing the performance of the subject device in a biological environment were additionally included to support substantial equivalence. The evaluation was a randomized, controlled study in an ovine model and was conducted in conformity with the Good Laboratory Practice for Non-Clinical Laboratory Studies (GLP) regulations of 21 CFR Part 58.

The 28-day *in vivo* evaluation studied the comparative performance and safety of the subject device as well as the untreated and unmodified predicate device (K080604) and the predicate BioFlo PICC with Endexo Technology (K140266). Study performance endpoints were in-life catheter patency and post-mortem vessel patency scores, device thrombus scores, and accumulated device thrombus weight. Safety endpoints studied included adverse events, gross pathology, and histopathology.

8. Clinical Performance Data.

No human clinical data was provided to support substantial equivalence.

9. Conclusion Regarding Substantial Equivalence

The information included in this premarket notification support the substantial equivalence of the subject Arrow Pressure-Injectable JACC with Sustain Technology to the stated predicate devices. The subject device has the same intended use, similar indications for use, incorporates the same fundamental technology, is composed of similar materials, and features a similar geometric design to the legally marketed predicate and reference devices to which it was compared.

In vitro performance and biocompatibility data were included to confirm the performance of the subject device against its physical design and performance requirements. Data from an *in vivo* evaluation confirmed the substantially equivalent performance of the subject device compared to the predicate devices in a biological environment.