DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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December 22, 2016

Arrow International, Inc. (a Subsidiary of Teleflex, Inc.)
Christine Ford
Senior Regulatory Affairs Manager
2400 Bernville Rd.
Reading, Pennsylvania 19605

Re: K160925
Trade/Device Name: VPS Rhythm™ Device with Optional TipTracker™ Technology
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long-Term Intravascular Catheter
Regulatory Class: II
Product Code: LJS
Dated: November 22, 2016
Received: November 28, 2016

Dear Christine Ford:

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
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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

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)*
K160925

Device Name

VPS Rhythm™ Device with Optional TipTracker™ Technology

Indications for Use *(Describe)*

The VPS Rhythm Device is indicated for the positioning of central venous catheters including PICCs. It provides catheter tip location information by using the patient's cardiac electrical activity. The VPS Rhythm Device is indicated for use as an alternative method to chest x-ray or fluoroscopy for confirmation of central venous catheter tip placement in adult patients. The TipTracker Technology is an optional accessory for use with the VPS Rhythm Device, indicated for visual navigation of a peripherally-inserted central catheter (PICC) as it is inserted through the vasculature. The TipTracker technology is used for catheter tip navigation purposes only; it is not used to determine final catheter tip placement.

Note: In general, devices that utilize ECG technique to observe P-wave are limited, but not contraindicated, for patients where cardiac rhythms may change presentation of the P-wave; including

- Atrial fibrillation
- Atrial flutter
- Severe tachycardia
- Pacemaker-driven rhythm
- Chronic obstructive pulmonary disease (COPD)

Such patients are easily identified prior to central catheter insertion. In these specific cases, use of an additional confirmation method is necessary 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.

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SECTION 6. 510(k) SUMMARY
VPS Rhythm Device with Optional TipTracker Technology

1. Applicant Information**:**

Arrow International (a subsidiary of Teleflex, Inc.)
2400 Bernville Rd.
Reading, PA 19605

Contact Person: Christine Ford
Telephone Number: (610) 378-0131, ext. 603338
Fax Number: (610) 478-3179
Date Prepared: 22-NOV-2016

2. Device Name:

- Proprietary Name: VPS Rhythm Device with Optional TipTracker Technology
- Common Name: Central catheter placement accessory
- Classification Name: Percutaneous, implanted long-term intravascular catheter.
- CFR Number: 21 CFR 880.5970
- Device Class: II
- Product Code: LJS (Catheter, Intravascular, long-term greater than 30 Days)

3. Predicate and Reference Device(s):

Predicate or Reference Device Name	**510(k)**	**Original Applicant Name**
PICC Tip Positioning Aid	K152261	Nostix LLC
Sherlock 3CG™ Tip Confirmation System	K140345	Bard Access Systems, Inc.
Nautilus Delta	K141634	Romedex

4. Description of Device:

The VPS Rhythm Device with Optional TipTracker Technology is a medical device system consisting of nonsterile, reusable electronic components and accessories, as well as single-use, sterile components. All of which are utilized together to facilitate the final confirmation of central venous catheter tip placement by using the patient's cardiac electrical waveform. The system features an electronic monitor with graphical user interface display, as well as connection cables and accessories which allow for the display of the patient's external and intravascular cardiac ECG waveforms. Interpretation - by the clinician - of changes in the patient's intravascular cardiac ECG waveform morphology, which are displayed in real-time on the VPS Rhythm Device monitor as the central venous catheter is inserted, is utilized for confirmation of the final position of the catheter tip as an alternative to radiographic confirmation.

With respect to the external and intravascular ECG waveform display functionality, the VPS Rhythm Device with Optional TipTracker Technology is identical to the predicate PICC Tip Positioning Aid (K152261). The subject VPS Rhythm Device incorporates the same monitor with graphical user interface, ECG Patient Cable, ECG snap leads, and ECG Clip Cable accessories as those cleared with the predicate PICC Tip Positioning Aid (K152261). The purpose of this premarket notification is for the introduction of the optional TipTracker Technology and associated components for PICC navigation as well as a clarification of the indications for use from the originally indicated use of ECG for final tip confirmation with PICCs only to use with central venous catheters in general for final catheter tip positioning.

The optional TipTracker Technology includes software algorithms and accessory components (the TipTracker T-piece and Stylet) which facilitate the real-time visualization of the catheter's track and direction as it is inserted by the clinician through the vasculature. The TipTracker T-piece is a non-sterile, reusable component consisting of a magnetic emitter array that is connected to the VPS Rhythm Device monitor. In use, the TipTracker T-piece is placed externally on the patient's chest. When the sterile, single-use TipTracker Stylet is assembled with the PICC which is to be inserted by the clinician, the VPS Rhythm Device with Optional TipTracker Technology facilitates the visualization of the catheter's insertion track and direction relative to the location of the TipTracker T-piece. The TipTracker Technology is not intended as an indicator of specific catheter location nor is it intended to be utilized for confirmation of final PICC tip location.

The TipTracker Stylet is to be provided sterile in a convenience kit for use with PICCs that are geometrically compatible. The TipTracker stylet may be used with PICCs that have a minimum internal distal lumen diameter of 0.018" or catheter sizes from 3-6 French. The TipTracker stylet may also be provided pre-loaded with ARROW PICC in ARROW convenience kits.

5. Indications for Use:

The VPS Rhythm Device is indicated for the positioning of central venous catheters including PICCs. It provides catheter tip location information by using the patient's cardiac electrical activity. The VPS Rhythm Device is indicated for use as an alternative method to chest x-ray or fluoroscopy for confirmation of central venous catheter tip placement in adult patients. The TipTracker Technology is an optional accessory for use with the VPS Rhythm Device, indicated for visual navigation of a peripherally-inserted central catheter (PICC) as it is inserted through the vasculature. The TipTracker technology is used for catheter tip navigation purposes only; it is not used to determine final catheter tip placement.

Note: In general, devices that utilize ECG technique to observe P-wave are limited, but not contraindicated, for patients where cardiac rhythms may change presentation of the P-wave including:

- Atrial fibrillation
- Atrial flutter
- Severe tachycardia
- Pacemaker-driven rhythm
- Chronic obstructive pulmonary disease (COPD)

Such patients are easily identified prior to central catheter insertion. In these specific cases, use of an additional confirmation method is necessary to confirm catheter tip location.

6. Substantial Equivalence

Intended Use / Indications for Use:
The subject VPS Rhythm Device with Optional TipTracker Technology has the same intended use as the predicate device. The subject and predicate device are intended to display the patient's external and intravascular ECG waveforms in order to allow the clinician to interpret changes in the patient's intravascular P-wave morphology as a central catheter is inserted through the vasculature towards the heart.

The indications for use of the subject device are identical (with the exception of the reference to central catheter type) to those of the predicate PICC Tip Positioning Aid (K152261) and similar to the reference device Sherlock 3CG™ Tip Confirmation System (K140345). The indications for use are similar to the Romedex Nautilus Delta (K141634) reference device in regards to placement of central venous access devices. All of the devices are indicated for providing real-time central catheter tip location information by using the patient's cardiac electrical activity as well as for use as an alternative method to chest x-ray or fluoroscopy confirmation of catheter tip placement.

Technological Characteristics:

The subject VPS Rhythm Device with Optional TipTracker Technology incorporates the same fundamental technology as the predicate and reference devices. The subject device as well as the predicate PICC Tip Positioning Aid (K152261) and the reference Sherlock 3CG™ Tip Confirmation System (K140345) incorporate electronic circuitry and software algorithms to acquire and display the patient's intravascular and external ECG waveforms in order to facilitate the confirmation of final central catheter tip placement as an alternative method to chest x-ray or fluoroscopy. Similarly, the reference Romedex Nautilus Delta (K141634) includes a patient module with integrated remote control for ECG data acquisition and processing; data is sent to a mobile platform via wireless (Bluetooth) technology for visualization of the patient's ECG information.

The subject VPS Rhythm Device with Optional TipTracker Technology and the predicate PICC Tip Positioning Aid (K152261) and the reference Sherlock 3CG Tip Confirmation System (K140345) include touch-screen graphical user interface displays; include remote control capability, and reusable components which facilitate the display of the patient ECG information. Similarly, the reference Romedex Nautilus Delta (K141634) includes an integrated remote control for ECG data acquisition and processing; the ECG data is sent to a mobile platform via wireless (Bluetooth) technology where it is displayed.

The subject VPS Rhythm Device with Optional TipTracker Technology and the reference Sherlock 3CG Tip Confirmation System (K140345) also include catheter insertion visualization in which magnetic field-based technology is utilized to allow the display of the relative position of the catheter's tip as it is inserted by the clinician. Both the

subject device and the reference Sherlock 3CG device (K140345) utilize a reusable accessory component which is placed on the patient's chest and a sterile, single-use stylet which is assembled with the catheter in order to facilitate the catheter tracking feature.

Table 6.1 summarizes the substantial equivalence comparison of the subject VPS Rhythm Device with Optional TipTracker Technology with the predicate and reference devices.

Table 6.1 – Substantial Equivalence Comparison Summary

Proposed Device VPS Rhythm Device with Optional TipTracker Technology	**Predicate Device** PICC Tip Positioning Aid (K152261)	**Reference Device** Sherlock 3CG™ Tip Confirmation System (K140345)	**Reference Device** Romedex Nautilus Delta (K141634)
Indications for Use: The VPS Rhythm Device is indicated for the positioning of central venous catheters including PICCs. It provides catheter tip location information by using the patient's cardiac electrical activity. The VPS Rhythm Device is indicated for use as an alternative method to chest x-ray or fluoroscopy for confirmation of central venous catheter tip placement in adult patients. The TipTracker Technology is an optional accessory for use with the VPS Rhythm Device, indicated for visual navigation of a peripherally-inserted central catheter (PICC) as it is inserted through the vasculature. The TipTracker technology is used for catheter tip navigation purposes only; it is not used to determine final catheter tip placement. Note: In general, devices that utilize ECG technique to	**Indications for Use:** The PICC Tip Positioning Aid is indicated for the positioning of peripherally inserted central catheters (PICCs) in adult patients. It provides real-time catheter tip location information by using the patient's cardiac electrical activity. The PICC Tip Positioning Aid is indicated for use as an alternative method to chest x-ray or fluoroscopy confirmation of PICC tip placement in adult patients. Note: In general, devices that utilize ECG technique to observe P-wave are limited, but not contraindicated, for patients where cardiac rhythms may change presentation of the P-wave; including - Atrial fibrillation - Atrial flutter - Severe tachycardia - Pacemaker-driven rhythm - Chronic obstructive	**Indications for Use:** The Sherlock 3CG Tip Confirmation System (TCS) is indicated for guidance and positioning of Peripherally Inserted Central Catheters (PICCs). The Sherlock 3CG TCS provides real-time PICC tip location information by using passive magnet tracking and the patient's cardiac electrical activity (ECG). When relying on patient's ECG signal, the Sherlock 3CG TCS is indicated for use as an alternative method to chest X-ray and fluoroscopy for PICC tip placement confirmation in adult patients. 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. In such patients, who are easily	**Indications for Use:** Nautilus Delta is indicated for navigation and positioning of central venous access devices (CVADs) of at least 3 Fr in size. Nautilus Delta provides real-time catheter tip location information by using the patient's cardiac electrical activity and is indicated for use as an alternative method to chest X-ray and fluoroscopy for CVAD tip placement confirmation. In adult patients and in adolescents (greater than 12 through 21 years of age), Nautilus Delta can be used with CVADs such as peripherally inserted central catheters (PICCs), central venous catheters (CVCs), implantable ports, and hemodialysis catheters; in children (greater than 2 to 12 years of age), Nautilus Delta can be used with PICCs and with centrally inserted central catheters (CICCs); in infants (greater than 1 month to 2 years of age) and in neonates (from birth to 1 month of age), Nautilus Delta can be used with CICCs. In each specific age group, the CVAD

technique to

Proposed Device VPS Rhythm Device with Optional TipTracker Technology	**Predicate Device** PICC Tip Positioning Aid (K152261)	**Reference Device** Sherlock 3CG™ Tip Confirmation System (K140345)	**Reference Device** Romedex Nautilus Delta (K141634)
observe P-wave are limited, but not contraindicated, for patients where cardiac rhythms may change presentation of the P-wave; including - Atrial flutter - Atrial fibrillation - Severe tachycardia - Pacemaker-driven rhythm - Chronic obstructive pulmonary disease (COPD). Such patients are easily identified prior to central catheter insertion. In these specific cases, use of an additional confirmation method is necessary to confirm catheter tip location.	pulmonary disease (COPD) Such patients are easily identified prior to central catheter insertion. Use of an additional confirmation method is necessary to confirm catheter tip location.	identifiable prior to catheter insertion, the use of an additional method is required to confirm PICC tip location.	type and size must be chosen and the CVAD must be used according to the CVAD's indications and instructions for use. Limiting but not contraindicated situations for this method 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. 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.
System Features and Components			
Monitor with touch screen graphical user interface.	Monitor with touch screen graphical user interface.	Monitor with touch screen graphical user interface.	Mobile medical software application running on a mobile platform which is used for display of surface and intracavitary ECG
Functionality for storage of insertion case information and subsequent printing by a USB printer.	Functionality for storage of insertion case information and subsequent printing by a USB printer.	Functionality for storage of insertion case information and subsequent printing by a USB printer.	Storage of data is on the on the mobile platform. The mobile application can send the data to a user-supplied Bluetooth printer.
Remote Control for clinician-inserter input and selection of display options.	Remote Control for clinician-inserter input and selection of display options.	Remote control for clinician input and selection of display options.	Patient module (ECG data acquisition and processing with integrated remote control); data is sent to a mobile platform via wireless (Bluetooth)

Proposed Device VPS Rhythm Device with Optional TipTracker Technology	**Predicate Device** PICC Tip Positioning Aid (K152261)	**Reference Device** Sherlock 3CG™ Tip Confirmation System (K140345)	**Reference Device** Romedex Nautilus Delta (K141634)
			technology.
TipTracker stylet for assembly with central venous catheter to allow visualization of catheter's insertion track and direction relative to the TipTracker T-piece magnetic emitter array. Stylet Design: Stylet Outer diameter: 0.015" Stylet Overall length : 29.5" (75 cm) Min. catheter lumen diameter compatibility: .018" (3-6 French catheters Sterile, single-use.	N/A	Sherlock 3CG stylet for assembly with central catheter to allow visualization of catheter's tip location and direction relative to the Sherlock 3CG magnetic field sensor. Stylet Design: Stylet Outer diameter: 0.019" Stylet Overall length : 78.5 cm Min. catheter lumen diameter compatibility: .020" Sterile, single-use.	N/A
TipTracker T-piece magnetic emitter array placed on patient's chest during catheter insertion. Facilitates passively-induced signal in TipTracker stylet's coiled tip when stylet (assembled with inserted catheter) enters the low power magnetic field.	N/A	3CG magnetic sensor placed on patient's chest during catheter insertion. Senses the permanent magnet in the 3CG™ stylet's tip (assembled with inserted catheter) when the inserted catheter is within sensing range.	N/A (this predicate supports only the use of the device's ECG technology for placement of CVADs, not catheter navigation)
Energy Source: -AC/DC power supply with removable hospital grade mains power cord - Rechargeable internal	Energy Source: -AC/DC power supply with removable hospital grade mains power cord - Rechargeable internal	Energy Source: -AC/DC power supply with hospital grade mains power cord - Rechargeable internal battery	Energy Source: - patient module: lithium polymer battery with USB cable for charging As determined by host device (mobile

Proposed Device VPS Rhythm Device with Optional TipTracker Technology	**Predicate Device** PICC Tip Positioning Aid (K152261)	**Reference Device** Sherlock 3CG™ Tip Confirmation System (K140345)	**Reference Device** Romedex Nautilus Delta (K141634)
Lithium-ion battery	Lithium-ion battery		platform) such as tablet/smartphone"
Sterile accessory convenience kits: Will include sterile convenience kits. • VPS Rhythm ECG Accessory Pack: Contains ECG clip cable, Remote Control cover, and commercially available ARROW-Johans ECG adapter. VPS TipTracker Stylet Accessory kit: Contains TipTracker stylet and Remote Control cover in sterile portion of kit. Contains T-piece cover and commercially available ECG surface electrodes in non-sterile portion of kit.	N/A	N/A	N/A

7. Non-Clinical Performance Data

Testing verifying the performance requirements of the subject VPS Rhythm Device with Optional TipTracker Technology was conducted and included in this premarket notification and the results support substantial equivalence. Testing included:

- IEC 60601-1, 3rd Edition – Electrical Safety
- IEC 60601-1-2, 3rd Edition – Electromagnetic Compatibility
- Software Verification and Validation Testing
- TipTracker Stylet Performance and Physical Integrity (after 1 year aging)
  - Tensile Strength
  - Flexural Integrity (ISO 11070)
  - Insertion and Withdrawal Force
  - Holding Force and Leak Resistance
  - Electrical Impedance and Voltage Feedback Testing
  - Corrosion Testing (ISO 11070)
  - PICC compatibility with TipTracker Stylet
  - TipTracker Stylet particulate Testing
- Sterile barrier package testing per ASTM F2096
- Sterilization residuals per ISO 10993-7

- Biocompatibility: According to the requirements identified in ISO 10993-1, biocompatibility testing on the patient contacting devices subject to this premarket notification is included. Testing was conducted for the assessment of cytotoxicity (ISO 10993-5), hemocompatibility (ISO 10993-4), sensitization and irritation (ISO 10993-10), and systemic toxicity (ISO 10993-11).
- Human Factors: A human factors study assessing the usability of the subject VPS Rhythm Device with Optional TipTracker Technology was conducted. The study utilized independent clinician participants to assess the primary operating functions of the proposed device against the predetermined usability criteria.

  The results of the human factors study were compiled and assessed in accordance with CDRH guidance, *Applying Human Factors and Usability Engineering to Medical Devices – Guidance for Industry and Food and Drug Administration Staff* (February 3, 2016) as well as with IEC 62366-1: *Medical devices – Part 1: Application of usability engineering to medical devices.*

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 supports the substantial equivalence of the subject VPS Rhythm Device with Optional TipTracker Technology to the stated predicate device. The listed reference devices provided substantial equivalence support for the catheter tracking portion of the device and the indications for use with central venous catheters for final tip confirmation using ECG technology. The subject device has the same intended use, similar indications for use and incorporates the same fundamental technology as the legally marketed predicate device and the reference devices to which it was compared.

Performance and biocompatibility data were included to verify the performance of the subject device against its physical design, functional, and safety requirements. The results of the testing included in this premarket notification support a determination of substantial equivalence.