August 22, 2022

Arrow International, LLC (a subsidiary of Teleflex, Inc.)
Elizabeth Duncan
Principal Regulatory Affairs Specialist
3015 Carrington Mill Blvd
Morrisville, North Carolina 27560

Re: K220363
Trade/Device Name: VPS Rhythm® DLX Device with TipTracker™ Technology
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, implanted, long-term intravascular catheter
Regulatory Class: Class II
Product Code: LJS
Dated: August 12, 2022
Received: August 12, 2022

Dear Elizabeth 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Payal Patel
Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220363

Device Name
VPS Rhythm® DLX Device with TipTracker™ Technology

Indications for Use *(Describe)*
The VPS Rhythm® DLX Device is indicated for the positioning of central venous catheters including PICCs. It provides real-time catheter tip location information by using the patient's cardiac electrical activity. The VPS Rhythm DLX® 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® DLX Device, indicated for visual navigation of a peripherally inserted central catheter (PICC) as it is threaded through the vasculature. The TipTracker™ technology is used for catheter tip navigation purposes only; it is not used to determine final catheter tip placement.

For a catheter insertion procedure, ultrasound may optionally be used to assess the blood vessel to aid in selection of catheter size and visualize the blood vessel during initial insertion.

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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K220363 - 510(k) SUMMARY
(per CFR 807.92)

VPS Rhythm® DLX Device with TipTracker™ Technology

1. Applicant Information**:**

Arrow International LLC (a subsidiary of Teleflex Incorporated)
3015 Carrington Mill Blvd.
Morrisville, NC 27560

Contact Person:	Elizabeth Duncan or Frank Pelc
Telephone Number:	(610) 781-6455 or 484-209-2172
Email:	elizabeth.duncan@teleflex.com or frank.pelc@teleflex.com

Date Prepared:	August 22, 2022

2. Device Name:

Trade/Proprietary Name:	VPS Rhythm® DLX Device with 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 Device(s):

Predicate Device Name	510(k)	Original Applicant Name
VPS Rhythm® Device with TipTracker™ Technology	K160925	Arrow International LLC

Reference Device(s):

Reference Device Name	510(k)	Original Applicant Name
Interson USB Ultrasound System	K163443	Interson Corporation

The reference device is used to specify the ultrasound probe that is optionally intended to attach to the proposed VPS Rhythm® DLX Device. The VPS Rhythm® DLX Device introduces the ability to pair the commercially available ultrasound probe (Interson Corporation, K163443) to permit ultrasound visualization during the initial central catheter insertion procedure for vessel assessment and visualization on the display of the VPS Rhythm® DLX system. No changes are being introduced to the Interson USB Ultrasound System.

4. Device Description:

The VPS Rhythm® DLX Device with 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® DLX 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.

The optional Tip TipTracker™ Technology includes the software algorithms and accessory components (the non-sterile, reusable TipTracker™ T-piece and sterile, single-use TipTracker™ and proposed NaviCurve™ Stylet) which facilitate the real-time visualization of a Peripherally Inserted Central Catheter's (PICC) track and direction as it is inserted by the clinician through the vasculature. The TipTracker™ T-piece consists of a magnetic emitter array that is connected to the VPS Rhythm® DLX Device monitor. In use, the TipTracker™ T-piece is placed externally on the patient's chest. When the sterile, single-use TipTracker™ Stylet or NaviCurve Stylet is assembled with the peripherally inserted central catheter (PICC) and inserted by the clinician, the VPS Rhythm® DLX Device with TipTracker™ Technology facilitates the visualization of the PICC'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 catheter tip location.
The proposed VPS Rhythm® DLX Device introduces the ability to pair a commercially available Ultrasound probe (Interson Corporation: K163443) with the VPS Rhythm® DLX monitor to permit ultrasound visualization during the initial central catheter insertion procedure for vessel assessment and visualization on the display of the VPS Rhythm® DLX system. An optional catheter to vessel ratio tool can be used during vessel assessment.

As a new optional feature related to P-wave morphology changes, the DLX Software uses a time detected reference based on the R-Peak to show where the P-wave should exist in a patient with a normal sinus rhythm.

5. Indications for Use:

Indications for Use:

The VPS Rhythm® DLX Device is indicated for the positioning of central venous catheters including PICCs. It provides real-time catheter tip location information by using the patient's cardiac electrical activity. The VPS Rhythm® DLX Device is indicated for use as an alternative method to chest x-ray or fluoroscopy confirmation of central venous catheter tip placement in adult patients.

The TipTracker™ Technology is an optional accessory for use with the VPS Rhythm® DLX Device, indicated for visual navigation of a peripherally inserted central catheter (PICC) as it is threaded through the vasculature. The TipTracker™ technology is used for catheter tip navigation purposes only; it is not used to determine final catheter tip placement.

For a catheter insertion procedure, ultrasound may optionally be used to assess the blood vessel to aid in selection of catheter size and visualize the blood vessel during initial insertion.

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.

Comparison of Intended Use / Indications for Use:

The subject device has the same intended use and technology as the predicate device, VPS Rhythm® Device with TipTracker™ Technology (K160925). The subject and predicate devices 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 addition of the optional use of Ultrasound for vessel assessment does not change the intended use or technology of the device as compared to the predicate. As demonstrated by the data included in this 510(k) submission, this difference is not critical to the intended use of the VPS Rhythm® DLX Device with TipTracker™ Technology and does not introduce any new safety or effectiveness concerns.

6. Comparison of Technological Characteristics with the Predicate Device:

The subject VPS Rhythm® DLX Device with TipTracker™ Technology incorporates the same fundamental technology as the predicate device. The subject device as well as the predicate (K160925) incorporate the same 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 to radiographic confirmation.

The subject VPS Rhythm® DLX Device with TipTracker™ Technology and the predicate device include touch-screen graphical user interface displays; include remote control capability, and reusable components which facilitate the display of the patient ECG information. The subject VPS Rhythm® DLX Device with TipTracker™ Technology also includes the same 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 and the predicate device utilize a reusable accessory component (T-Piece) 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.

With respect to the external and intravascular ECG waveform display functionality, the VPS Rhythm® DLX Device with TipTracker™ Technology is identical to the predicate VPS Rhythm® Device (K160925). The purpose of this premarket notification is for the introduction of an additional sterile, single-use navigation stylet for use with the optional TipTracker™ Technology and associated

components, new monitor, software and cybersecurity upgrades, workflow modifications to allow for fewer system interactions and a pairing with a commercially available ultrasound probe (K163443), upgraded ECG Patient Cable to function with the DLX device.

Table 6.1 summarizes the substantial equivalence comparison of the subject VPS Rhythm® Device with TipTracker™ Technology with the predicate devices.

Table 6.1 – Substantial Equivalence Comparison Summary

Technological Characteristic	**Proposed Device** VPS Rhythm® DLX Device with TipTracker™ Technology	**Predicate Device** VPS Rhythm® Device with Optional TipTracker™ Technology (K160925)	**Substantial Equivalence Assessment of Modifications**
System Description	Displays the patient's surface (external) ECG waveform to the monitor via three (3) electrode leads. Displays the patient's intravascular ECG waveform to the monitor through the Remote Control cable via connection of an ECG clip cable to the central catheter's placement wire/stylet, or to the saline column in a central catheter's distal lumen via the commercially available ARROW-Johans ECG adapter. Intravascular ECG waveform is also transmitted through the navigation stylets. Includes TipTracker™ Technology which facilitates display of a PICC's tip insertion track and direction relative to the T-piece magnetic emitter array. The sterile, single-use navigation stylet is assembled with a PICC. A signal is passively induced in the stylet's inner distal coil when the stylet's tip enters the T-piece magnetic field. Device software triangulates the passively induced signal with respect to the T-piece magnetic array to derive the catheter tip's insertion track and direction. Includes a connection that provides the ability to attach/pair an Ultrasound transducer for use in assessing the vasculature during a CVAD placement procedure.	Same as predicate with the exception of the ability to connect an Ultrasound transducer	Justification for no S&E impact: the ability to attach a commercially available ultrasound probe to has no impact on the safety and effectiveness of the VPS Rhythm DLX device since the Ultrasound feature/display is independent of the primary functionality of the VPS Rhythm DLX device, which is placement of a central catheter using TipTracker™ Technology for navigation and ECG technology for final tip placement and confirmation, which is the same as the predicate. Compatibility testing of the ultrasound probe with the VPS Rhythm DLX system demonstrated there are no new safety or efficacy concerns.
Monitor	- DLX Monitor- Off-the-shelf single board computer with custom main board electronic circuitry and software with a **12"** touch screen graphical user interface to display surface (external) and intravascular patient ECG waveforms, catheter insertion track and direction relative to the T-piece magnetic emitter array accessory. Includes a connection port for the	- Rhythm Monitor Off-the-shelf single board computer with custom main board electronic circuitry and software with **8"** touch screen graphical user interface to display surface (external) and intravascular patient ECG waveforms as well as catheter insertion track and direction relative to the	Justification for no S&E impact: The larger screen and ultrasound probe connection port modifications have no impact on the use or functionality of the VPS Rhythm® DLX device per its intended use as demonstrated by appropriate system testing of the VPS Rhythm® DLX system with these

Technological Characteristic	**Proposed Device** VPS Rhythm® DLX Device with TipTracker™ Technology	**Predicate Device** VPS Rhythm® Device with Optional TipTracker™ Technology (K160925)	**Substantial Equivalence Assessment of Modifications**
	attachment of an Ultrasound probe to provide the ability to display **ultrasound images when the commercially available ultrasound probe is connected.** - A **custom LEMO** USB port allows connection of a **USB ultrasound probe** and two standard USB ports for a USB printer and USB memory stick to facilitate printing and PDF export of stored case information. • Standard Lemo Ports **customized** to aid customers in determining which accessory connects to which port/socket for the connection of Remote Control, ECG Patient Cable and T-piece to the DLX monitor.	T-piece magnetic emitter array accessory. - **Standard** USB ports allow connection of USB printer and USB memory stick to facilitate printing and PDF export of stored case information. • Standard Lemo Ports allow connection of Remote Control, ECG Patient Cable and T-piece to the Rhythm monitor.	modifications which supports that there are no new safety or efficacy concerns.
Remote Control	- Remote Control Non-sterile, reusable component for connection to monitor allows clinician-inserter selection of display options. Remote control connector to the monitor has been modified to connect to the DLX monitor.	- Remote Control **SAME** as the proposed device with the exception of the connector.	Justification for no S&E impact: same as described under Monitor.
ECG components	- ECG Patient cable: Non-sterile provides a connection to the monitor on one end, and to the ECG snap leads at the other - Connector has been modified to connect to the DLX monitor - ECG snap leads Non-sterile (1.5mm DIN- style connectors) for surface (external) ECG. - ECG clip cable Sterile for connection to central catheter placement wire or placement stylet to	- ECG patient cable **SAME** as the proposed device with the exception of the connector - ECG snap leads **SAME** as the proposed device - ECG clip cable **SAME** as the proposed device	Justification for no S&E impact: same as described under Monitor.

Technological Characteristic	**Proposed Device** VPS Rhythm® DLX Device with TipTracker™ Technology	**Predicate Device** VPS Rhythm® Device with Optional TipTracker™ Technology (K160925)	**Substantial Equivalence Assessment of Modifications**
	obtain intravascular ECG. - ECG Electrode Pads – Non-sterile, disposable, commercially-available, off the shelf ECG pads for snap leads to connect to transmit signal.	- ECG Electrode Pads **SAME** as the proposed device	
Navigation Stylets	**-TipTracker™ Stylet** (cleared under K160925—no changes presented in this submission): Provided: Sterile and for single use Electrical Output: When inserted into a PICC, allows visualization of the catheter's insertion track and direction relative to the TipTracker™ T-piece magnetic emitter array accessory. Transmits intravascular electrocardiogram (ECG) information during insertion. - Stylet Outside Diameter Spec: 0.015" - Stylet Overall Length: 30.58" - Contains Curve Profile: No - Contains Flexible Tip: No - **NaviCurve™ Stylet** Provided: Sterile and for single use Electrical Output: When inserted into an Arrow PICC, allows visualization of the catheter's insertion track and direction relative to the	**TipTracker™ Stylet: SAME** as proposed device	Justification for no S&E impact for the NaviCurve Stylet: The NaviCurve stylet has the same intended use and functionality as the predicate TipTracker™ stylet for use with the TipTracker™ Technology to allow visualization of the catheter as it advances through the vessel during an insertion procedure. Neither stylet is indicated for use in final catheter tip placement confirmation. The minimal specification changes described do not introduce new concerns of safety and effectiveness as demonstrated by the V&V testing performed, including Human Factors/ Usability testing.

Technological Characteristic	**Proposed Device** VPS Rhythm® DLX Device with TipTracker™ Technology	**Predicate Device** VPS Rhythm® Device with Optional TipTracker™ Technology (K160925)	**Substantial Equivalence Assessment of Modifications**
	TipTracker™ T-piece magnetic emitter array accessory. Transmits intravascular electrocardiogram (ECG) information during insertion. - Stylet Outside Diameter Spec: 0.018” - Stylet Overall Length: 32-13/32” - Contains Curve Profile: Yes - Contains Flexible Tip: Yes		
T-piece	- DLX T-piece magnetic emitter array placed on patient’s chest during catheter insertion. Facilitates passively induced signal in navigation stylet’s coiled tip when stylet (assembled with inserted PICC) enters the low-power magnetic field. Connector has been modified from the predicate to connect to the DLX monitor.	- Rhythm T-piece **SAME as PROPOSED DEVICE** except for connector.	Justification for no S&E impact: same as described under Monitor
ECG Region Feature	- P-wave region highlight feature-optional feature related to P-wave morphology changes captured through a snapshot, the DLX Software uses a time detected reference based on the R-Peak to show where the P-wave should exist in a patient with a normal sinus rhythm.	-NA	Justification for no S&E impact: The P-wave region highlight feature is an optional tool for clinician use that must be turned on to be functional if the clinician chooses to use it. This feature does not indicate the presence of a P-wave. It only identifies the region where the P-wave should exist for a patient with normal sinus rhythm. It remains the clinician’s responsibility to use their judgement to identify P-wave morphology changes when determining final catheter tip location, which is the

Technological Characteristic	**Proposed Device** VPS Rhythm® DLX Device with TipTracker™ Technology	**Predicate Device** VPS Rhythm® Device with Optional TipTracker™ Technology (K160925)	**Substantial Equivalence Assessment of Modifications**
			same as that required for the predicate device.
Ultrasound Connection Capability	• The VPS Rhythm® DLX provides the ability to optionally pair/attach a commercially available ultrasound probe (Interson Corporation, K163443) to permit ultrasound visualization during the initial central catheter insertion procedure for vessel assessment and needle insertion on the display of the VPS Rhythm® DLX system. • In ultrasound mode, an optional catheter-to-vessel ratio tool is provided.	-NA	Justification for no S&E impact: The use of the commercially available Interson Ultrasound probe (K163443) is an optional tool for clinician use. There are no modifications to the Interson probe functionality associated with this VPS Rhythm® DLX 510(k). Use of Ultrasound is independent of the ECG and navigational features of the proposed device and is not a required step for successful tip placement. Compatibility testing of the ultrasound probe with the VPS Rhythm® DLX system demonstrated there are no new safety or efficacy concerns. The catheter-to-vessel ratio tool is an optional feature the clinician chooses to use if desired. The tool does not determine the size of catheter to use; it provides a visual display for the clinician to consider when determining the catheter size for the patient, and calculates catheter occlusion area based on the vessel size and catheter size selected by the clinician when viewing the catheter-to-vessel ratio tool overlay on the ultrasound display (the device does not make any decisions on size). It remains the clinician's responsibility to use their judgement to choose the right catheter for the patient, which is the same as that required for the predicate device.

Technological Characteristic	**Proposed Device** VPS Rhythm® DLX Device with TipTracker™ Technology	**Predicate Device** VPS Rhythm® Device with Optional TipTracker™ Technology (K160925)	**Substantial Equivalence Assessment of Modifications**
Energy Source	- Energy Source: AC/DC power supply [18V 40W] with removable hospital grade mains power cord. - Rechargeable internal Lithium-ion battery [11V 74W-hr].	Similar AC/DC power supply [12V 20W] with **SAME AS PROPOSED DEVICE** removable hospital grade mains power cord. Similar rechargeable Lithium-ion battery [7.2V 63 W-hr].	Justification for no S&E impact: The power supply and battery modifications were tested as part of the system testing (IEC 60601-1 safety testing) and demonstrated acceptable results, supporting that there are no different concerns of safety or efficacy as a result of these modifications.
Software	Programming environment: Windows-based host development system comprised of: a) Visual Studio 2017 running on Windows 10 PC b) Advantech SOM-6869 single board computer. c) Azure DevOps cloud-based development services; including code repository, defect tracking, code review, continuous integration, build/configuration management. Operating Environment: The DLX system software runs on the Windows 10 IoT Enterprise 2019 LTSC operating system for an X64-based single board computer. It utilizes the Windows Presentation Foundation (WPF), .Net and C# to create the graphical user interface (GUI), application program interface (API) and both a remote and a touchscreen interface as the basis for its human machine interface. Workflow modifications to minimize the number of system interactions	Programming environment: a) QNX 6.4.1 Momentics Development Platform running on Windows XP or Linux. b) Advantech PCM-3353 single board computer. c) Perforce P4V source code control management system. d) Configuration Management, Issue Tracking, and Collaboration System based on Atlassian software development tools. Operating Environment: The Rhythm system software runs on the QNX 6.4.1 real-time operating system for an X86	Justification for no S&E impact: All software changes were tested and evaluated through V&V and Human Factors testing and demonstrated acceptable results, supporting that there are no different concerns of safety or efficacy as a result of these modifications.

Technological Characteristic	**Proposed Device** VPS Rhythm® DLX Device with TipTracker™ Technology	**Predicate Device** VPS Rhythm® Device with Optional TipTracker™ Technology (K160925)	**Substantial Equivalence Assessment of Modifications**
Notifications/ Alerts	Alerts may occur in ECG and Tracking modes, on the Case Manager screen, during device startup, and when battery is low. New alerts:-Replace coin cell battery -Ultrasound probe not connected	Some alerts have different visual notification of these alerts from the proposed device.	Justification for no S&E impact: Although the visual notification may appear slightly different, all alerts provided in the predicate device are also present in the proposed device with identical functionality and with no change in procedural workflow to address the alert messages. The added Replace coin cell battery alert would appear only when the system is initially powered on, resulting in no difference to procedural workflow and no change to safety or performance of the device. The Ultrasound probe not connected alert was added only due to the addition of the optional ultrasound probe connection and is a simple notice that the US probe must be connected to use the Ultrasound feature. There is no different issue of safety and effectiveness related to this alert since the use of Ultrasound is optional. Even if it was not possible to use the Ultrasound, the catheter placement procedure using the VPS Rhythm® DLX device could still be fully conducted using TipTracker™ Technology for catheter tracking and ECG technology for final tip placement—same as for the predicate.

7. Non-Clinical Performance Data

Testing verifying the performance requirements of the subject VPS Rhythm® DLX Device with 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, 4th Edition – Electromagnetic Compatibility
- Software Verification and Validation Testing
- Cybersecurity assessments conducted in accordance with the FDA *Guidance for Industry and Staff: Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, Draft Guidance for Industry and Food and Drug Administration Staff, Draft Guidance, 2018*
- VPS Rhythm® DLX device performance and physical integrity testing:
  - Accessory Compatibility
  - Essential Performance: Distortion, Screen Freezing, ECG Impedance, ECG Waveform Performance
  - ECG Display
  - Tracking Display
  - Ultrasound Display
  - Chemical Resistance
  - Cleaning and Disinfection
  - Flex life of cable connectors (ANSI/AAMI EC53)
  - Tensile strength of cable connections (ANSI/AAMI EC53)
  - Shock Testing of Monitor, T-piece, Remote Control (IEC 60068-2-27)
  - Sinusoidal Vibration of Monitor, T-piece and Remote Control (IEC 60068-2-6)
  - Random Vibration of Monitor, T-piece and Remote Control (IEC 60068-2-64)
  - Dielectric withstand voltage of T-piece, Remote Control and ECG Patient Cable (ANSI/AAMI EC53)
- Navigation Stylet performance and physical integrity testing per FDA Guidance: *Coronary, Peripheral, and Neurovascular Guidewires – Performance Tests and Recommended Labeling, Guidance for Industry and Food and Drug Administration Staff,* 2019:
  - Tensile Strength
  - Flexural Integrity (ISO 11070)
  - Insertion and Withdrawal Force

- Corrosion (ISO 11070)
- Particulate Evaluation
- Coating Integrity
- Torque
- Radiopacity
- Kink Resistance
- Holding Force and Leak Resistance
- Electrical Impedance and Voltage Feedback Testing

- Biocompatibility according to the requirements identified in ISO 10993-1, and *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices-Part 1: Evaluation and testing within a Risk Management Process: Guidance for Industry and Food and Drug Administration Staff,* 2020. Biocompatibility testing on the patient contacting devices subject to this premarket notification is included. For skin contacting devices, testing was conducted for the assessment of cytotoxicity (ISO 10993-5) and sensitization and irritation (ISO 10993-10); for circulating blood contacting devices, those tests as well as hemocompatibility (ISO 10993-4) and systemic toxicity (ISO 10993-11) were conducted. The patient contacting materials as part of the subject device are intended for a duration of less than 24 hours.

- Human Factors: A human factors and usability report assessing the usability of the subject VPS Rhythm® DLX Device with TipTracker™ Technology was conducted. The studies conducted 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*, 2016; as well as with IEC 62366-1: *Medical devices – Part 1: Application of usability engineering to medical devices*.

Clinical Performance Data

No human clinical data was provided to support substantial equivalence.

8. Conclusion

The information included in this premarket notification supports the substantial equivalence of the subject VPS Rhythm® DLX Device with TipTracker™ Technology to the stated predicate device. The subject device has the same intended use and technology as the legally marketed predicate device to which it was compared.

Performance, Human Factors/Usability, Biocompatibility, and safety testing has been conducted and has passed all acceptance criteria to verify that the proposed VPS Rhythm® DLX Device with TipTracker™ Technology meets its design, physical integrity, functional, software, and safety requirements and that any dimensional or material differences between it and the predicate devices do not raise new issues of safety and effectiveness. The results of the testing included in this premarket notification support a determination of substantial equivalence.

It is concluded that the information provided in this discussion supports a conclusion of Substantial Equivalence of the proposed VPS Rhythm® DLX Device with TipTracker™ Technology to the VPS Rhythm® Device with TipTracker™ Technology.