January 31, 2025

C. R. Bard, Inc.
Caitlin Bowles
Senior Regulatory Affairs Specialist
8195 Industrial Blvd.
Covington, Georgia 30014

Re: K241334
Trade/Device Name: Bard® Temporary Pacing Electrode Catheter
Needle / Cannula (Introducer)
Regulation Number: 21 CFR 870.3680
Regulation Name: Cardiovascular Permanent Or Temporary Pacemaker Electrode
Regulatory Class: Class II
Product Code: LDF, DYB
Dated: January 3, 2025
Received: January 3, 2025

Dear Caitlin Bowles:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Jessica L. Batista -S

Digitally signed by Jessica L. Batista -S
Date: 2025.01.31 16:58:40 -05'00'

for

Sara Royce
Assistant Director
Division of Cardiac Electrophysiology, Diagnostics, and Monitoring Devices
Office of Cardiovascular 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)*
K241334

Device Name
Bard® Temporary Pacing Electrode Catheter
Needle / Cannula (Introducer)

Indications for Use *(Describe)*
Bard® Temporary Pacing Catheters are designed to transmit an electrical signal from an external pulse generator to the heart or from the heart to a monitoring device.
The Needle / Cannula (Introducer) is intended for the introduction of Bard® Temporary Pacing Electrode Catheters into the venous vasculature.

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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510(k) Summary - K241334

In accordance with 21 CFR §807.92, a 510(k) summary upon which substantial equivalence determination is based is as follows:

Submitter	C. R. Bard, Inc. 8195 Industrial Blvd Covington, GA 30014 Establishment Registration # - 1018233
Contact Person	Caitlin Bowles Senior Regulatory Affairs Specialist Telephone Number: 470-205-9024
Date Prepared	December 30, 2024
Subject Devices	Trade Name: Bard® Temporary Pacing Electrode Catheter Common / Usual Name: Temporary pacemaker electrode Classification Name: Cardiovascular permanent or temporary pacemaker electrode, 21 CFR §870.3680 Product Code: LDF Regulatory Classification: II Trade Name: Needle / Cannula (Introducer) Common / Usual Name: Catheter introducer Classification Name: Catheter introducer, 21 CFR §870.1340 Product Code: DYB Regulatory Classification: II
Predicate Devices	Legally marketed device to which substantial equivalence is claimed for Bard® Temporary Pacing Electrode Catheters: • Primary Predicate: USCI® Special Care Pacing Electrode and USCI® Bipolar Balloon Pacing Electrode with BH (benzalkonium heparin) Coating – K955712 (C. R. Bard, Inc.) Legally marketed device to which substantial equivalence is claimed for the Needle / Cannula (Introducer): • Primary Predicate: Prelude Pursuit™ Splittable Sheath Introducer – K172117 (Merit Medical Systems, Inc.)

Device Description

Bard® Temporary Pacing Electrode Catheters:

Bard® Temporary Pacing Catheters are designed to transmit an electrical signal from an external pulse generator to the heart or from the heart to a monitoring device.

Bard® Temporary Pacing Electrode Catheters are constructed of insulated electrical wires encased within a woven shaft, which is then coated with various blends of radiopaque polyurethane-based materials. All Temporary Pacing Electrode Catheters are bipolar and include two stainless steel electrodes - one located along the shaft and one at the catheter distal tip. The proximal end of the devices includes the two electrical leads which have shrouded jacks and are used to establish electrical connections with an external pulse generator or monitoring device.

Some products may be packaged with accessories such as a needle / cannula, an ECG adapter, or a balloon inflation syringe. All Bard® Temporary Pacing Catheter devices are packaged with safety adapters, are intended for prescription use only, and are for single use only.

Needle / Cannula (Introducer):

The Needle / Cannula (Introducer) is intended for the introduction of Bard® Temporary Pacing Electrode Catheters into the venous vasculature. The Needle / Cannula (Introducer) is not sold separately by C. R. Bard, Inc. and this accessory is only included with certain Bard® Temporary Pacing Electrode Catheter kits. The devices are provided in two different French size / length variants, dependent on size / type of the accompanying Bard® Temporary Pacing Electrode Catheter.

The Needle / Cannula (Introducer) includes a needle and a cannula. The two components of the Introducer are inserted into the vein simultaneously. The needle in then withdrawn, leaving in place the cannula, through which the Bard® Temporary Pacing Electrode Catheter can be advanced through the vessel and into the desired placement location. The device is intended for prescription use only and is for single use only.

Indications for Use

Bard® Temporary Pacing Electrode Catheters:

Bard® Temporary Pacing Catheters are designed to transmit an electrical signal from an external pulse generator to the heart or from the heart to a monitoring device.

Needle / Cannula (Introducer):

The Needle / Cannula (Introducer) is intended for the introduction of Bard® Temporary Pacing Electrode Catheters into the venous vasculature.

The Bard® Temporary Pacing Electrode Catheters and predicate device (primary predicate, K955712) feature the same intended use: transmitting a pacing electrical stimulus from the pulse generator to the heart and/or to transmit the electrical signal of the heart to the pulse generator.

The indications for use are specifically for introduction of Bard® Temporary Pacing Electrode Catheter pacing leads.

The subject device and primary predicate (K172117) are introducers and feature the same intended use: facilitating placing a catheter through the skin into a vein.

Comparison of Technological Characteristics

Bard® Temporary Pacing Electrode Catheters:

Comparisons of the Bard® Temporary Pacing Electrode Catheters without balloons (subject), Bard® Temporary Pacing Electrode Catheters with balloons (subject), and the predicate device are provided in Table 1.

Table 1. Comparison of the Subject (Bard® Temporary Pacing Electrode Catheters without balloons) and Predicate (USCI® Special Care Pacing Electrode and USCI® Bipolar Balloon Pacing Electrode with Benzalkonium-heparin (BH) Coating) Devices

Design / Technological Characteristic	**Subject Device:** **Bard® Temporary Pacing Electrode Catheters without balloons** **Bard® Temporary Pacing Electrode Catheters with balloons**	**Predicate Device (K955712):** **USCI® Special Care Pacing Electrode** **USCI® Bipolar Balloon Pacing Electrode**
FDA Clearance Number	Subject of this submission	K955712
FDA Product Code	LDF (Electrode, Pacemaker, Temporary)	LDF (Electrode, Pacemaker, Temporary)
Labeling Characteristics		
Indications for Use	Bard® Temporary Pacing Catheters are designed to transmit an electrical signal from an external pulse generator to the heart or from the heart to a monitoring device.	The USCI® Pacing Electrodes are used to transmit a pacing electrical stimulus from the pulse generator to the heart and/or transmit an electrical stimulus from the heart to a recording device.
Recommended maximum duration for temporary pacing	The intended lifetime of use for Bard® Temporary Pacing Catheters is up to 11 days. Note: Real-world clinical evidence for the subject device has demonstrated substantial equivalence up to this 11 day maximum duration.	Per labeling: N/A – Not stated on labeling. Note: the predicate submission included discussion on duration of use, and the duration of the subject device falls within the same timeframe as duration of use for the predicate device.
General Characteristics		
Sterilization Method	Ethylene oxide Note: OEM product codes 108154P and 106173P are sterilized by the purchaser before marketing	Ethylene oxide
Single Use Only	Yes	Yes
Non-pyrogenic	Yes	Yes

Design / Technological Characteristic	**Subject Device:** **Bard® Temporary Pacing Electrode Catheters without balloons** **Bard® Temporary Pacing Electrode Catheters with balloons**	**Predicate Device (K955712):** **USCI® Special Care Pacing Electrode** **USCI® Bipolar Balloon Pacing Electrode**
Materials		
Electrodes	Stainless steel	Stainless steel
Electrical Tail Pins / Jacks	Gold plated brass	Tin plated brass
Electrical Tail Pins / Jack Overmolding	Polypropylene	N/A
Shaft	Polyurethane	Polyurethane
Coating	N/A – No coating	Benzalkonium Heparin (BH)
Bifurcate	Black Polyethylene	Black Polyethylene
Balloon *(variants with balloon only)*	Natural rubber latex	Natural rubber latex
Stopcock *(variants with balloon only)*	Polyethylene and polycarbonate	Polyethylene and polycarbonate
Balloon Tie Thread *(variants with balloon only)*	Polyester	Polyester
Dimensions / Specifications		
Balloon Feature *(variants with balloon only)*	Yes – 1.5 mL volume	Yes – 1.5 mL volume
Distal Configuration	Variants without balloon: Curved Variants with balloon: Straight or Right Heart Curve	Variants without balloon: Curved Variants with balloon: Straight or Right Heart Curve
Distal Tip Type	Variants without balloon: Standard material used for shaft distal tip (non-patient contacting) or Soft distal tip material used for shaft distal tip (non-patient contacting)	Variants without balloon: Standard material used for shaft distal tip (non-patient contacting)

Design / Technological Characteristic	Subject Device: Bard® Temporary Pacing Electrode Catheters without balloons Bard® Temporary Pacing Electrode Catheters with balloons	Predicate Device (K955712): USCI® Special Care Pacing Electrode USCI® Bipolar Balloon Pacing Electrode
	Variants with balloon: Standard material used for shaft distal tip (non-patient contacting)	Variants with balloon: Standard material used for shaft distal tip (non-patient contacting)
French Sizes	Variants without balloon: 4 – 7 French Variants with balloon: 4 – 5 French (Straight tip); 5 French (Right Heart Curve)	Variants without balloon: 4 – 5 French Variants with balloon: 4 – 5 French (Straight tip); 5 French (Right Heart Curve)
Lengths (Overall)	Variants without balloon: 100cm, 125cm, 132cm Variants with balloon: 126cm	Variants without balloon: 132cm Variants with balloon: 126cm
Lengths (Usable)	Variants without balloon: 83cm, 108cm, 115cm Variants with balloon: 110cm	Variants without balloon: 115cm Variants with balloon: 110cm
Electrodes (Number and spacing)	Bipolar (2 electrodes) Variants without balloon: 1st electrode at distal tip with 2nd electrode 1cm proximal or 1st electrode at distal tip with 2nd electrode 2.5cm proximal Variants with balloon: 1st electrode at distal tip with 2nd electrode 1cm proximal	Bipolar (2 electrodes) Variants without balloon: 1st electrode at distal tip, 2nd electrode 1cm proximal Variants with balloon: 1st electrode at distal tip with 2nd electrode 1cm proximal
Radiopaque	Yes	Yes
Accessories	Introducer (Needle / Cannula) (Included with certain models only) – *also subject to this submission* Safety Lead Adapter (Included with all models) ECG Adapter (Included with certain models only) Ballon Inflation Syringe (Included with all models with balloons)	Introducer (Needle / Cannula) ECG Adapter

Design / Technological Characteristic	Subject Device: Bard® Temporary Pacing Electrode Catheters without balloons Bard® Temporary Pacing Electrode Catheters with balloons	Predicate Device (K955712): USCI® Special Care Pacing Electrode USCI® Bipolar Balloon Pacing Electrode
Introducer Compatibility	Via a Needle Cannula Introducer (or percutaneous introducer sheath - not sold or provided by C. R. Bard, Inc.). One of two introducer variants may be provided with some products based on the French size of the Bard® Temporary Pacing Electrode Catheter.	Via a Needle Cannula, Hemaquet™ Sterile-lock Introducer, or USCI Percutaneous Catheter Introducer Per IFU (variants without balloon): French size designation of the introducer reflects the maximum outer diameter of a catheter or temporary transvenous pacing lead that the introducer sheath will accept. Per IFU (variants with balloon): Introducer French size provided is dependent on the balloon electrode French size.

Needle / Cannula (Introducer):

A comparison of the Needle / Cannula (Introducer) to the primary predicate (K172117) is provided in Table 2.

Table 2. Comparison of the Subject (Introducer (Needle / Cannula) Used with Bard® Temporary Pacing Electrode Catheters and Primary Predicate (Prelude Pursuit™ Splittable Sheath Introducer)

Design / Technological Characteristic	Subject Device: Introducer (Needle / Cannula)	Primary Predicate Device (K172117): Prelude Pursuit™ Splittable Sheath Introducer
FDA Clearance Number	Subject of this submission	K172117
FDA Product Code	DYB (Introducer, Catheter)	DYB (Introducer, Catheter)
Indications for Use	The Needle / Cannula (Introducer) is intended for the introduction of Bard® Temporary Pacing Electrode Catheters into the venous vasculature.	The introduction of various types of pacing/defibrillator leads and catheters into the venous vasculature.

Design / Technological Characteristic	Subject Device: Introducer (Needle / Cannula)	Primary Predicate Device (K172117): Prelude Pursuit™ Splittable Sheath Introducer
General Characteristics		
Principles of Operation	"Over the needle" operation mechanism. The introducer catheter tubing is positioned with a glove fit over the needle tubing, and the needle protrudes from the end of the cannula tubing to create initial access. The two components of the Introducer are inserted into the vein simultaneously. The needle is then withdrawn, leaving in place the cannula, through which the Temporary Pacing Electrode Catheter can be advanced through the vessel and into the desired placement location.	Introducer needle is inserted into the vessel. Guidewire is inserted through the needle into the vessel and needle is removed, leaving the guidewire in place. The dilator / introducer sheath assembly is advanced over the guidewire and into the vessel. Once the assembly is fully introduced into the venous system, the guidewire and dilator are retracted, leaving the introducer sheath in position, through which the catheter / pacing lead can be advanced into position.*
Sterilization Method	Ethylene oxide	Ethylene oxide
Single Use Only	Yes	Yes
Device Specific Characteristics		
Splittable Sheath	No	Yes
Accessories / Components	Introducer catheter, Introducer needle, Needle guard (Removed prior to use)	Introducer sheath, Dilator, Guidewire, Introducer needle, Syringe or Introducer sheath, Dilator
Compatibility	Introduction of Bard® Temporary Pacing Electrode Catheters	Introduction of various types of pacing/defibrillator leads and catheters
Materials		
Introducer catheter	Fluorinated Ethylene Propylene (FEP) with Barium Sulfate with high density polyethylene hub	Polymers – formulation undisclosed
Introducer needle	Stainless steel needle with polypropylene hub	Stainless steel needle with polymer hub

Design / Technological Characteristic	Subject Device: Introducer (Needle / Cannula)	Primary Predicate Device (K172117): Prelude Pursuit™ Splittable Sheath Introducer
Dimensions / Specifications		
Introducer catheter inner diameter (minimum)	Variant I - 5.3 French Variant II - 6.5 French	5 – 16 French
Introducer catheter length	Variant I - 6.7 to 8.3 cm Variant II - 5.1 to 5.7 cm	13 & 25 cm
Introducer needle outer diameter	Variant I - 16G Variant II - 14G	18G
Introducer needle length Predicate only: Dilator length (for reference)	Variant I - 9.3 cm Variant II - 7.5 cm	7 cm Dilator: 7.59” or 19.3 cm (13cm introducer) and 12.34” or 31.3 cm (25 cm introducer)
** = Information extracted from current IFU for Prelude Prestige™ [Pursuit] devices via firm’s website (https://www.merit.com/product/prelude-prestige-splittable-sheath-introducer/#documents_education) on 16 April 2024.*		

Performance Data Summary

Bard® Temporary Pacing Electrode Catheters:

1. Biocompatibility Testing
   Biocompatibility testing on the subject devices was carried out in alignment with the requirements for an External Communicating – Circulating Blood contacting device with prolonged contact duration per ISO 10993-1:2018. The subject device was determined to be biocompatible for its intended use.

2. Performance Testing

   Certain endpoints (as applicable) of the following standards have been deemed relevant to Bard® Temporary Pacing Electrode Catheter performance:

   - ISO 10555-1:2013 [AMD 2017] - Intravascular catheters - Sterile and single-use intravascular catheters - Part 1: General requirements
   - IEC 60601-1:2020 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
   - IEC 60601-1-2:2020 - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

- ISO 80369-1:2018 - Small-bore connectors for liquids and gases in healthcare applications - Part 1: General requirements
- ISO 80369-7:2021 - Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications
- ISO 80369-20:2015 - Small-bore connectors for liquids and gases in healthcare applications - Part 20: Common test methods

To demonstrate intended device performance, as well as to support the substantial equivalence of the subject Bard® Temporary Pacing Electrode Catheters to the predicate device, the technological and performance characteristics were evaluated by completion of the below testing endpoints:

- Radio-detectability (ASTM F640)
- Surface inspection
- Corrosion Resistance
- Freedom from Leakage *(Bard® Temporary Pacing Electrode Catheters with balloons only)*
- Peak Tensile Force
- Electrical safety and electromagnetic compatibility as applicable to a Type CF applied part when used with an external pulse generator as a system in the professional healthcare facility intended use environment
- Female luer lock on stopcock component of Bard® Temporary Pacing Electrode Catheters with balloons only:
    - Dimensional requirements of small-bore connectors
    - Functional testing of small-bore connectors
- Ability of balloon to be inflated with balloon inflation syringe (Bard® Temporary Pacing Electrode Catheters with balloons only)
- Bard® Temporary Pacing Electrode Catheter functionality with the Needle / Cannula (Introducer) accessory
- System Verification / Interoperability
- Lifetime of Use / Duration of Pacing – Electrical functionality after exposure to simulated use conditions
- Electrical continuity and insulation resistance
- Balloon inflated diameter
- Balloon leak resistance
- Balloon reliability: leak resistance after worst-case number of inflation / deflation cycles, mechanical inflation / deflation cycling to failure, and cumulative air injection to failure.

The subject Bard® Temporary Pacing Electrode Catheter devices met the requirements of the above standards and performance endpoints, and were substantially equivalent to the predicate device for other performance testing completed.

Needle / Cannula (Introducer):

1. Biocompatibility Testing
   Biocompatibility testing on the subject devices was carried out in alignment with the requirements for an External Communicating – Circulating Blood contacting device with prolonged contact duration per ISO 10993-1:2018. The subject device was determined to be biocompatible for its intended use.

2. Performance Testing

   As with the predicate device, the subject devices have also undergone various types of functionality testing per ISO 11070 to demonstrate no impact to device performance. Certain endpoints (as applicable) of the following standards have been deemed relevant to Needle/Cannula (Introducer) performance:

   - ISO 11070:2014 - Sterile single-use intravascular introducers, dilators and guidewires
   - ISO 80369-1:2018 - Small-bore connectors for liquids and gases in healthcare applications - Part 1: General requirements
   - ISO 80369-7:2021 - Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications
   - ISO 80369-20:2015 - Small-bore connectors for liquids and gases in healthcare applications - Part 20: Common test methods

   To demonstrate intended device performance, as well as to support the substantial equivalence of the subject Needle/Cannula (Introducer) to the predicate device, the technological and performance characteristics were evaluated by completion of the below testing endpoints:

   - Surface inspection of Introducer Needle and Introducer catheter
   - Corrosion Resistance of Introducer needle
   - Needle Point inspection
   - Strength of Union of Needle Tube and Needle Hub
   - Tip of Introducer Needle and Introducer catheter
   - Peak Tensile Force of Introducer catheter
   - Dimensional requirements of small-bore connectors
   - Functional testing of small-bore connectors
   - Needle / Cannula (Introducer) functionality with Bard® Temporary Pacing Electrode Catheters
   - System Verification / Interoperability
   - Lifetime of Use – Introducer functionality after exposure to simulated use conditions

   The subject Introducer (Needle / Cannula) used with Bard® Temporary Pacing Electrode Catheter devices met the requirements of the above standards and performance endpoints, and were substantially equivalent to the predicate device for performance testing completed.

Conclusion

Bard® Temporary Pacing Electrode Catheters:

The subject Bard® Temporary Pacing Electrode Catheters are substantially equivalent to the legally marketed predicate device as demonstrated by the same indications for use and similar / equivalent design features as the predicate device, USCI® Special Care Pacing Electrode and USCI® Bipolar Balloon Pacing Electrode with Benzalkonium-heparin (BH) Coating (K955712). The subject device is substantially equivalent to the legally marketed predicate device, and nonclinical test data / real-world clinical evidence demonstrate that the subject device is substantially equivalent and that any differences in technological characteristics do not raise different questions of safety and effectiveness.

Needle / Cannula (Introducer):

The subject Needle / Cannula (Introducer) is substantially equivalent to the legally marketed predicate device as demonstrated by the same indications for use and similar / equivalent design features as the primary predicate device Prelude Pursuit™ Splittable Sheath Introducer (K172117). The subject device is substantially equivalent to the legally marketed predicate device, and nonclinical test data demonstrates that the subject device is substantially equivalent and that any differences in technological characteristics do not raise different questions of safety and effectiveness.