May 15, 2025

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

Re: K251186
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: April 16, 2025
Received: April 16, 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,

Sara M. Royce -S
Digitally signed by Sara M. Royce -S
Date: 2025.05.15 09:01:40 -04'00'

Sara Royce
Assistant Director
DHT2A: Division of Cardiac Electrophysiology, Diagnostics, and Monitoring Devices
OHT2: 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251186

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.

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

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510(k) Summary - K251186

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	May 15, 2025
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 Device	Legally marketed device to which substantial equivalence is claimed for Bard® Temporary Pacing Electrode Catheters and Needle / Cannula (Introducer): • Primary Predicate: Bard® Temporary Pacing Electrode Catheters and Needle / Cannula (Introducer) – K241334 (C. R. Bard, 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. Certain catheters may incorporate a lumen for balloon inflation.

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 is 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 and Intended 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 subject Bard® Temporary Pacing Electrode Catheters and Needle / Cannula (Introducer) and the predicate device, Bard® Temporary Pacing Electrode Catheters and Needle / Cannula (Introducer) (primary predicate, K241334), feature the same indications for use detailed above. For the Needle / Cannula (Introducer), the indications for use are specifically for introduction of Bard® Temporary Pacing Electrode Catheter pacing leads.

The subject Bard® Temporary Pacing Electrode Catheters and the predicate device, Bard® Temporary Pacing Electrode Catheters (primary predicate, K241334), 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 subject Needle / Cannula (Introducer) and the predicate device, Needle /

Cannula (Introducer) (primary predicate, K241334), feature the same intended use: *facilitating placing a catheter through the skin into a vein.*

The Bard® Temporary Pacing Electrode Catheters and Needle / Cannula (Introducer) are substantially equivalent to the legally marketed predicate device as demonstrated by the identical intended use and indications for use.

Comparison of Technological Characteristics

The subject device shares the following similarities to the predicate device:

- Identical intended use.
- Identical indications for use.
- Identical technological characteristics / design features.

The subject device has the following differences from the predicate device:

- Removal of warning from labeling regarding unknown electromagnetic compatibility (EMC) with electronics capable of generating low-frequency emissions.

Other than the labeling change to remove the low-frequency emissions EMC warning, there are no other labeling or design changes versus the predicate device (K241334) clearance that would result in a new 510(k).

Comparisons of the Bard® Temporary Pacing Electrode Catheters and Needle / Cannula (Introducer) (subject) and the Bard® Temporary Pacing Electrode Catheters and Needle / Cannula (Introducer) (primary predicate, K241334) are provided in Table 1.

This comparison is abbreviated to include only the intended use, indications for use, and the specific characteristics changing which are subject to this Special 510(k) submission (labeling warning removal / electromagnetic compatibility compliance). All other design or technological characteristics in-scope of the 510(k) Summary of the predicate (K241334) remain unchanged.

Table 1. Comparison of the Subject (Bard® Temporary Pacing Electrode Catheters and Needle / Cannula (Introducer)) and Predicate (Bard® Temporary Pacing Electrode Catheters and Needle / Cannula (Introducer)) Devices

Design / Technological Characteristic	Subject Device: Bard® Temporary Pacing Electrode Catheters and Needle / Cannula (Introducer)	Predicate Device (K241334): Bard® Temporary Pacing Electrode Catheters and Needle / Cannula (Introducer)
FDA Clearance Number	Subject of this submission	K241334
Classification Regulation	21 CFR § 870.3680 – Cardiovascular permanent or temporary pacemaker electrode 21 CFR § 870.1340 – Catheter introducer	21 CFR § 870.3680 – Cardiovascular permanent or temporary pacemaker electrode 21 CFR § 870.1340 – Catheter introducer

Design / Technological Characteristic	Subject Device: Bard® Temporary Pacing Electrode Catheters and Needle / Cannula (Introducer)	Predicate Device (K241334): Bard® Temporary Pacing Electrode Catheters and Needle / Cannula (Introducer)
FDA Product Code	LDF (Electrode, Pacemaker, Temporary) DYB (Introducer, Catheter)	LDF (Electrode, Pacemaker, Temporary) DYB (Introducer, Catheter)
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 Needle / Cannula (Introducer) is intended for the introduction of Bard® Temporary Pacing Electrode Catheters into the venous vasculature.	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.
Warnings	Not Applicable – Warning removed from instructions for use.	Warning: The Bard® Temporary Pacing Electrode Catheter is partially compliant with IEC 60601-1-2 Edition 4.1 and its electromagnetic compatibility with electronics capable of generating low-frequency emissions such as mobile phones, wireless power transfer (i.e., wireless charging pads), radio-frequency identification devices (RFID), etc., is currently unknown. Additional precautions should be taken to ensure these low-frequency electromagnetic emission sources are not within the vicinity of the temporary pacing system during its intended use. In the presence of excessive levels of electromagnetic interference, the external pulse generator may exhibit degraded performance that may diminish or disrupt cardiac pacing. Refer to the external pulse generator instructions for use for further information on how to identify performance degradations and how to resolve or mitigate performance degradations.

Design / Technological Characteristic	Subject Device: Bard® Temporary Pacing Electrode Catheters and Needle / Cannula (Introducer)	Predicate Device (K241334): Bard® Temporary Pacing Electrode Catheters and Needle / Cannula (Introducer)
General Characteristics		

Electromagnetic compatibility	Electromagnetic compatibility was evaluated 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.
	
	Testing to IEC 60601-1-2, including:
	
	• Radiated Emissions
	  ○ CISPR11 ed6.2 (2015 +A1:2016 +A2:2019)
	• Electro-Static Discharge Immunity Test
	  ○ IEC 61000-4-2 ed2.0 (2008-12)
	• Radiated, Radiofrequency, Electromagnetic Immunity
	  ○ IEC 61000-4-3 ed3.0 (with A1:2007+A2:2010)
	• Immunity to proximity fields from RF wireless communications equipment
	  ○ Table 9 of IEC 60601-1-2 using the test methods specified in IEC 61000-4-3
	• Conducted, Radiofrequency, Electromagnetic Immunity Test
	  ○ IEC 61000-4-6 ed4.0 (2013)
	• Power Frequency Magnetic Field Immunity Test
	  ○ IEC 61000-4-8 ed2.0 (2009-09)
	• Immunity to Proximity Magnetic Fields
	  ○ Table 11 of IEC 60601-1-2 using the test methods specified in IEC 61000-4-39 (2017)
		Electromagnetic compatibility was evaluated 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.
		
		Testing to IEC 60601-1-2, including:
		
		• Radiated Emissions
		  ○ CISPR11 ed6.2 (2015 +A1:2016 +A2:2019)
		• Electro-Static Discharge Immunity Test
		  ○ IEC 61000-4-2 ed2.0 (2008-12)
		• Radiated, Radiofrequency, Electromagnetic Immunity
		  ○ IEC 61000-4-3 ed3.0 (with A1:2007+A2:2010)
		• Immunity to proximity fields from RF wireless communications equipment
		  ○ Table 9 of IEC 60601-1-2 using the test methods specified in IEC 61000-4-3
		• Conducted, Radiofrequency, Electromagnetic Immunity Test
		  ○ IEC 61000-4-6 ed4.0 (2013)
		• Power Frequency Magnetic Field Immunity Test
		  ○ IEC 61000-4-8 ed2.0 (2009-09)

Performance Data Summary

Certain endpoints of consensus standard IEC 60601-1-2 have been deemed relevant to support the change subject to this submission. Electromagnetic compatibility testing of the subject Bard® Temporary Pacing Electrode Catheter devices was conducted per the applicable requirements of the following standard:

- IEC 60601-1-2 (Edition 4.1): 2020 - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
    - IEC 60601-1-2 Clause 8.11, Immunity to Proximity Magnetic Fields
        - Table 11 of IEC 60601-1-2 using the test methods specified in IEC 61000-4-39 (2017)

Electromagnetic compatibility testing confirmed that the subject Bard® Temporary Pacing Electrode Catheters met electromagnetic compatibility requirements as defined in IEC 60601-1-2 Clause 8.11 for Immunity to Proximity Magnetic Fields. Verification activities included testing of the device when used as a system with representative external pulse generator equipment.

Consistent with the predicate device (K241334), standard IEC 60601-1-2 Edition 4.1 was utilized to evaluate electromagnetic compatibility. Testing was completed per compendial methods detailed within IEC 60601-1-2 Edition 4.1 Clause 8.11(d) (IEC 61000-4-39: 2017) per applicable specifications in Table 11. Representative external pulse generator equipment and the sample Temporary Pacing Electrode devices utilized were consistent with other IEC 60601-1-2 immunity testing performed as part of the predicate (K241334) clearance. Acceptance criteria were the same as the acceptance criteria utilized for other IEC 60601-1-2 immunity testing performed as part of the predicate (K241334) clearance.

Therefore, electromagnetic compatibility with electronics capable of generating low-frequency emissions has been demonstrated, and the subject device remains substantially equivalent to the predicate (K241334) device.

Conclusion

The subject Bard® Temporary Pacing Electrode Catheters and Needle / Cannula (Introducer) are substantially equivalent to the legally marketed predicate device as demonstrated by the identical intended use / indications for use and same technological characteristics / design features as the predicate device, Bard® Temporary Pacing Electrode Catheters and Needle / Cannula (Introducer) (K241334). The labeling modification to remove a warning regarding unknown electromagnetic compatibility with electronics capable of generating low-frequency emissions does not raise any different questions of safety and effectiveness. Well-established methods were utilized to confirm the subject devices' electromagnetic compatibility with electronics capable of generating low-frequency emissions, and the data demonstrate substantial equivalence to the legally marketed predicate device.