September 29, 2026

BridgeSource Medical Corporation
John Walmsley
Staff Scientist
3301 Northland Dr.
Suite 214
Austin, Texas 78751

Re: DEN260007
Trade/Device Name: SmartRead™ Medical Device Identifier (4100)
Regulation Number: 21 CFR 870.3645
Regulation Name: Cardiac device identifier
Regulatory Class: Class II
Product Code: SJJ
Dated: March 23, 2026
Received: March 24, 2026

Dear John Walmsley:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the SmartRead™ Medical Device Identifier (4100), a prescription device under 21 CFR Part 801.109 with the following indications for use:

> The SmartRead™ Medical Device Identifier is intended to determine the manufacturer of an unknown cardiac implanted electronic device (CIED) manufactured by Abbott Laboratories, Biotronik, Boston Scientific Corporation, Medtronic, or Microport.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the SmartRead™ Medical Device Identifier (4100), and substantially equivalent devices of this generic type, into Class II under the generic name cardiac device identifier.

FDA identifies this generic type of device as:

> **Cardiac device identifier**. A cardiac device identifier is a noninvasive device that is intended to provide information about implanted cardiac devices. The device detects and matches telemetry based on manufacturer-specific wireless communication signals, including radiofrequency or inductive signals, to identify an implanted cardiac device, including manufacturer, model, or type. The device is not intended to deliver therapeutic stimulation to, modify the programming of, or manipulate the stored data of the implanted device.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On March 24, 2026, FDA received your De Novo requesting classification of the SmartRead™ Medical Device Identifier (4100). The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the SmartRead™ Medical Device Identifier (4100) into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request, FDA has determined that, for the previously stated indications for use, the SmartRead™ Medical Device Identifier (4100) can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Identified Risks to Health	**Mitigation Measures**
Electric shock / injury	Electrical safety testing
Device failure/malfunction leading to inappropriate treatment	Non-clinical performance testing Labeling
Implanted device misidentification leading to delayed care	Software verification, validation, and hazard analysis Electromagnetic compatibility testing Labeling
Unintended interference or changes to implanted device functions leading to inappropriate therapy	Non-clinical performance testing
Infection	Labeling
Adverse tissue reaction	Biocompatibility evaluation

In combination with the general controls of the FD&C Act, the cardiac device identifier is subject to the following special controls:

(1) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. Testing must include the following:
   (A) Identification accuracy testing must show that the device correctly identifies the implanted cardiac device (e.g., manufacturer, device type, or model, according to the indications for use); and

(B) Testing must evaluate performance across all cardiac devices from manufacturers labeled to be compatible with the device and across the device's specified effective communication range.

(2) Non-clinical performance testing must demonstrate that the device does not adversely affect the function of cardiac devices, including that:
   (A) No permanent or temporary alteration of implanted cardiac device sensing, pacing, or other therapy parameters occurs during or after device communication, tested under worst-case use conditions, to include multiple consecutive interactions;
   (B) No adverse effect on implanted cardiac device function occurs when the device is used in proximity to implanted cardiac devices that are incompatible with the device's communication protocol, either by testing or an engineering analysis under clinically relevant device conditions;
   (C) The device does not transmit commands that alter implanted cardiac device programming;
   (D) Multiple consecutive interactions (e.g., 10) does not impact the battery life of the cardiac device; and
   (E) The device does not enable unauthorized access to, or unintended programming of, implanted cardiac devices during or after a communication session. The device must not transmit therapeutic commands.

(3) Performance testing must demonstrate the electrical safety and electromagnetic compatibility of the device.

(4) The device must be demonstrated to be biocompatible.

(5) Labeling must include the following:
   (A) A statement that the device is for device identification purposes only and does not provide therapeutic functions;
   (B) A list of implanted cardiac device types and manufacturers whose signals the device is intended to detect, the verified detection accuracy of the device, and any known limitations in detection;
   (C) Warnings regarding use in patients with multiple implanted devices and the potential for ambiguous identification; and
   (D) Cleaning instructions.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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).

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type.

FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the cardiac device identifier they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C 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 Management System Regulation (QMSR) (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 FD&C Act; 21 CFR 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.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, 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).

If you have any questions concerning the contents of the letter, please contact Mark Bolton at 301-837-7216.

Sincerely,

HETAL B. ODOBASIC -S

Hetal Odobasic
Director
Division of Cardiac Electrophysiology,
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Office of Cardiovascular Devices
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