September 12, 2025

Boston Scientific Corporation
Melissa Klamerus
Principal Regulatory Affairs Specialist
4100 Hamline Avenue North
Saint Paul, Minnesota 55112

Re: K252593
Trade/Device Name: LUX-Dx II Insertable Cardiac Monitor (M302); LUX-Dx II+ Insertable Cardiac Monitor (M312)
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector And Alarm (Including ST-Segment Measurement And Alarm)
Regulatory Class: Class II
Product Code: MXD
Dated: August 15, 2025
Received: August 15, 2025

Dear Melissa Klamerus:

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: 2025.09.12 13:25:16 -04'00'

Jessica Batista Bertolini
Acting 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252593

Device Name
LUX-Dx II Insertable Cardiac Monitor (M302);
LUX-Dx II+ Insertable Cardiac Monitor (M312)

Indications for Use *(Describe)*
The LUX-Dx Insertable Cardiac Monitor (ICM) is intended to monitor and record subcutaneous electrocardiogram (S-ECG). The recorded S-ECG is used for the clinical evaluation and diagnosis of cardiac arrhythmias. The LUX-Dx is indicated for use in patients that have a known heart condition and are at risk of developing an abnormal heart rhythm, or have symptoms that may suggest a cardiac arrhythmia, such as dizziness, palpitations, syncope, chest pain, and/or shortness of breath. The LUX-Dx ICM is indicated for atrial fibrillation monitoring in patients that have been previously diagnosed or treated for atrial fibrillation.

The LUX-Dx has not been tested specifically for pediatric use.

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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Boston Scientific
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Tel: (651) 582-4000
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510(k) Summary

1. SUBMITTER

Boston Scientific Corporation
4100 Hamline Avenue North
St. Paul, Minnesota 55112-5798

Contact: Emily Bailey
Senior Regulatory Specialist
Phone: (952) 500-1763
Email: emily.bailey@bsci.com

Date Prepared: 11-September-2025

2. DEVICE

Trade Names: LUX-Dx II™ Insertable Cardiac Monitor (M302) and LUX-Dx II+™ Insertable Cardiac Monitor (M312)
Common Name: Arrythmia detector and alarm
Product Code/Panel: MXD, Cardiovascular
Device Class and Panel: Class II
Classification Regulation: 21 CFR 870.1025

3. PREDICATE DEVICE

Trade Name: LUX-Dx II™ Insertable Cardiac Monitor and LUX-Dx II+™ Insertable Cardiac Monitor
Manufacturer: Boston Scientific Corp
Clearance Number: K231328, 19-Aug-2023
Common Name: Arrythmia detector and alarm
Product Code/Panel: MXD, Cardiovascular
Device Class and Panel: Class II
Classification Regulation: 21 CFR 870.1025

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4. INDICATION FOR USE

The LUX-Dx Insertable Cardiac Monitor (ICM) is intended to monitor and record subcutaneous electrocardiogram (S-ECG). The recorded S-ECG is used for the clinical evaluation and diagnosis of cardiac arrhythmias. The LUX-Dx is indicated for use in patients that have a known heart condition and are at risk of developing an abnormal heart rhythm, or have symptoms that may suggest a cardiac arrhythmia, such as dizziness, palpitations, syncope, chest pain, and/or shortness of breath. The LUX-Dx ICM is indicated for atrial fibrillation monitoring in patients that have been previously diagnosed or treated for atrial fibrillation.

The LUX-Dx has not been tested specifically for pediatric use.

5. RATIONALE FOR DIFFERENCE FROM PREDICATE PER 21 CFR 807.92(A)(5)

The Indication for Use statement includes additional clarifying language that differs from the predicate device. The additional language clarifies the patient population but does not alter it in any way. The intended use also remains the same and there are no new or increased risks associated with the additional language.

6. DEVICE DESCRIPTION

The LUX-Dx II and LUX-Dx II+ ICM devices evaluate S-ECG waveform data for indications of cardiac arrhythmias and "marks" the S-ECG signal for clinical presentation and evaluation when the algorithm criteria are met. The ICM device is inserted into the subcutaneous layer of the fourth intercostal space of the left chest wall. The ICM device is powered by an integrated battery. The LUX-Dx system includes the following main components:

- ICM device - a subcutaneously-implanted cardiac monitor device for cardiac arrhythmia event data collection and transmission. In addition, symptom events are collected and transmitted from the device.
- Mobile Monitor (MM) - mobile applications (myLUX™ Patient app and LUX-Dx™ Clinic Assistant app) running on an OTS mobile device that communicates with the ICM device (using Bluetooth Low Energy (BLE)) and the LATITUDE Clarity™ server (using cellular/Wi-Fi) for collection and transmission of event, patient, and device data.
- LATITUDE Clarity™ server - a server that communicates with the Mobile Monitor for bidirectional data transmission and provides web access for clinicians to perform remote monitoring activities and manage general patient and system parameters and workflow activities.
- System Accessories- for insertion of the ICM device, an insertion tool and incision tool are provided. In addition, a magnet is provided to initiate ICM/MM app communication.

7. SUBSTANTIAL EQUIVALENCE

Category	Predicate (K231328)	Proposed	Comments
Device Name (Model)	LUX-Dx II Insertable Cardiac Monitor (M302) LUX-Dx II+ Insertable Cardiac Monitor (M312)	LUX-Dx II Insertable Cardiac Monitor (M302) LUX-Dx II+ Insertable Cardiac Monitor (M312)	Identical
Pro Code / Regulation	MXD, 21 CFR 870.1025 Recorder, Event, Implantable Cardiac, (With Arrhythmia Detection)	MXD, 21 CFR 870.1025 Recorder, Event, Implantable Cardiac, (With Arrhythmia Detection)	Identical

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Category	Predicate (K231328)	Proposed	Comments
	Special controls: Class II Special Controls Guidance - Arrhythmia Detector and Alarm, Oct 2003	Special controls: Class II Special Controls Guidance - Arrhythmia Detector and Alarm, Oct 2003	
Indication for Use	The LUX-Dx Insertable Cardiac Monitor (ICM) is intended to monitor and record subcutaneous electrocardiogram (S-ECG). The recorded S-ECG is used for the clinical evaluation and diagnosis of cardiac arrhythmias. The LUX-Dx is indicated for use in patients that have a known heart condition and are at risk of developing an abnormal heart rhythm, or have symptoms that may suggest a cardiac arrhythmia such as dizziness, palpitations, syncope, chest pain, and/or shortness of breath. The LUX-Dx has not been tested specifically for pediatric use.	The LUX-Dx Insertable Cardiac Monitor (ICM) is intended to monitor and record subcutaneous electrocardiogram (S-ECG). The recorded S-ECG is used for the clinical evaluation and diagnosis of cardiac arrhythmias. The LUX-Dx is indicated for use in patients that have a known heart condition and are at risk of developing an abnormal heart rhythm, or have symptoms that may suggest a cardiac arrhythmia such as dizziness, palpitations, syncope, chest pain, and/or shortness of breath. The LUX-Dx ICM is indicated for atrial fibrillation monitoring in patients that have been previously diagnosed or treated for atrial fibrillation. The LUX-Dx has not been tested specifically for pediatric use.	Substantially Equivalent.
Use	Single Use	Single Use	Identical
Sterility	Supplied Sterile (EtO)	Supplied Sterile (EtO)	Identical
MR Status	MR Conditional (1.5T and 3T)	MR Conditional (1.5T and 3T)	Identical
Energy Source	Battery powered: Lithium-manganese dioxide (LiMnO2)	Battery powered: Lithium-manganese dioxide (LiMnO2)	Identical
Longevity	3 years	3 years	Identical
Materials of Construction	Body (Can) Material: Titanium Electrodes: Titanium Nitride Header: Implantation-grade Polymer, Epoxy MC31L Coating: Parylene	Body (Can) Material: Titanium Electrodes: Titanium Nitride Header: Implantation-grade Polymer, Epoxy MC31L Coating: Parylene	Identical
Dimensions	Volume: 1.2 cc Mass: 3 grams Dimensions 7.2 x 44.8 x 4.0 (mm)	Volume: 1.2 cc Mass: 3 grams Dimensions 7.2 x 44.8 x 4.0 (mm)	Identical
System Communication	Wireless telemetry using standard communication protocols: - Bluetooth Low Energy (BLE) - Cellular - Wi-Fi	Wireless telemetry using standard communication protocols: - Bluetooth Low Energy (BLE) - Cellular - Wi-Fi	Identical
Accessories Packaged with the Device	Implant Tools (single use & supplied sterile) - Incision Tool: polycarbonate, stainless steel - Insertion Tool: polycarbonate	Implant Tools (single use & supplied sterile) - Incision Tool: polycarbonate, stainless steel - Insertion Tool: polycarbonate	Identical

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Category	Predicate (K231328)	Proposed	Comments
Other Accessories	Mobile Device Software Apps - myLUX Patient Apps (2925, 2929, 2939) - Clinic Assistant App (2935) LATITUDE Clarity Server Software (7260) Magnet in Shielded Box (6386) myLUX Patient Kit (6385; magnet in shielded box + patient literature)	Mobile Device Software Apps - myLUX Patient Apps (2925, 2929, 2939) - Clinic Assistant App (2935) LATITUDE Clarity Server Software (7260) Magnet in Shielded Box (6386) myLUX Patient Kit (6385; magnet in shielded box + patient literature)	Identical
Detection Algorithms	Atrial Fibrillation (AF) Tachycardia (Tachy) Bradycardia (Brady) Pause Atrial Tachycardia (AT) Premature Ventricular Contraction (PVC)	Atrial Fibrillation (AF) Tachycardia (Tachy) Bradycardia (Brady) Pause Atrial Tachycardia (AT) Premature Ventricular Contraction (PVC)	Identical
Monitoring	Remote	Remote	Identical
Mobile Device Options	Bring Your Own Device (BYOD) - Android - Apple iOS Boston Scientific Provided Mobile Device - Android	Bring Your Own Device (BYOD) - Android - Apple iOS Boston Scientific Provided Mobile Device - Android	Identical

8. SUMMARY OF PERFORMANCE TESTING

No performance testing necessary.

9. CONCLUSION

Based on the intended use, fundamental technological characteristics, and performance testing, the proposed LUX-Dx II and LUX-Dx II+ have been shown to be appropriate for the intended use and are considered to be substantially equivalent to the predicate device.