August 19, 2023

Boston Scientific Corp
Emily Jallen
Senior Regulatory Affairs Specialist
4100 Hamline Ave North
St. Paul, Minnesota 55112

Re: K231328
Trade/Device Name: LUX-Dx II (M302); LUX-Dx II+ (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: July 17, 2023
Received: July 18, 2023

Dear Emily Jallen:

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,

Sara M. Royce -S
Digitally signed by Sara M. Royce -S
Date: 2023.08.19 20:33:18 -04'00'

Sara Royce
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: 06/30/2023
*See PRA Statement below.*

Submission Number *(if known)*

K231328

Device Name

LUX-Dx II (M302);
LUX-Dx II+ (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 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.**

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# 510(k) Summary

## 1. Submitter

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

Contact: Emily Jallen
Senior Regulatory Specialist
Phone: 651.581.1565
Email: emily.jallen@bsci.com

Date Prepared: 12 July 2023

## 2. Device

Trade Names: LUX-Dx II™ Insertable Cardiac Monitor and LUX-Dx II+™ Insertable Cardiac Monitor
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™ Insertable Cardiac Monitor
Manufacturer: Boston Scientific Corp
Clearance Number: K193473, 26 June 2020
Common Name: Arrythmia detector and alarm
Product Code/Panel: MXD, Cardiovascular
Device Class and Panel: Class II
Classification Regulation: 21 CFR 870.1025

## 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 has not been tested specifically for pediatric use.

## 5. Device Description

The LUX-Dx II (M302) and LUX-Dx II+ (M312) 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 electrodes used for detecting the S-ECG signal are located on each end of the ICM device, in the header and at the base of the 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.

## 6. Technological Characteristics

The intended use, principles of operation, and fundamental technology remain unchanged from the predicate LUX-Dx M301 ICM device. In addition, there are no changes to the ICM device hardware or physical characteristics as part of this 510(k) Notification. The changes incorporated into the LUX-Dx ICM device models (M302, M312) include new and enhanced detection algorithms, bring-your-own-device (BYOD) capability, and additional changes for sustaining/maintenance and continuous improvement.

The LUX-Dx ICM device models (M302, M312) include a PVC detection algorithm as well as an enhancement to the Pause algorithm to reduce the potential for false positive detections. The M312 ICM device model also includes an enhancement to the AF algorithm to reduce the potential for false positive detections. In

addition, both ICM device models (M302, M312) allow for the use of a personal mobile device (referred to as BYOD) as part of the LUX-Dx system.

## 7. Substantial Equivalence

In support of a substantial equivalence determination, BSC has evaluated the differences between the LUX-Dx II M302 and LUX-Dx II+ M312 ICM devices and the predicate LUX-Dx ICM M301, K193473. Based on the indications for use, fundamental technological characteristics, and performance testing, the LUX-Dx ICM device models (M302, M312) have been shown to be appropriate for the intended use and are substantially equivalent to the predicate device.

| Characteristic | Predicate: Model M301 LUX-Dx ICM | Model M302 LUX-Dx II ICM<br>Model M312 LUX-Dx II+ ICM |
|---|---|---|
| **Indications 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.<br>The LUX-Dx has not been tested specifically for pediatric use. | Identical |
| **Usage** | Single use | Identical |
| **Sterility** | Supplied sterile | Identical |
| **Volume Dimension** | 1.2 cc | Identical |
| **MR Conditional** | 1.5 T and 3T | Identical |
| **Energy Source** | Battery powered - $LiMnO_2$ | Identical |
| **Longevity** | 3 years | Identical |
| **Arrythmias Detected** | • AF<br>• Tachy<br>• Brady<br>• Pause<br>• AT | • AF<br>• Tachy<br>• Brady<br>• Pause<br>• AT<br>• PVC |
| **Remote Monitoring** | Yes | Identical |
| **Packaging** | Sterile kit including ICM device and custom implant tools<br>Accessories: External, non-sterile devices are packaged separately | Identical |

## 8. Summary of Performance Testing

Boston Scientific performed safety risk management activities, design verification, design validation, and usability testing to demonstrate that the LUX-Dx system meets the design intent, conforms to user needs and intended use, and supports substantial equivalence to the predicate device. Testing to support the changes for the LUX-Dx ICM device models (M302, M312) includes system and sub-system design verification testing, various software validations, cybersecurity testing, human factors/usability, and design validation testing including algorithm validation.

## 9. Conclusion

Based on the intended use, fundamental technological characteristics, and performance testing, LUX-Dx II M302 and LUX-Dx II+ M312 have been shown to be appropriate for the intended use and are substantially equivalent to the predicate device.