June 26, 2020

Boston Scientific Corporation
Melissa Klamerus
Principal Regulatory Affairs Specialist
4100 Hamline Ave North
St. Paul, Minnesota 55112

Re: K193473
Trade/Device Name: LUX-Dx™ Insertable Cardiac Monitor
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: June 10, 2020
Received: June 12, 2020

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 (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,

for

Jennifer Shih Kozen
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193473

Device Name
LUX-Dx™ Insertable Cardiac Monitor

Indications for Use *(Describe)*
The LUX-Dx Insertable Cardiac Monitor (ICM) is intended to monitor and record subcutaneous ECG (S-ECG) for the clinical evaluation and diagnosis of cardiac arrhythmias. The LUX-Dx is indicated for use in patients that have a known heart condition, are at risk of developing an abnormal heart rhythm, or have symptoms that may suggest a heart condition 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.

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

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510(k) Summary

1. Submitter

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

Contact: Melissa Klamerus
Principal Regulatory Specialist
Phone: (651) 582-6771
Email: melissa.klamerus@bsci.com

Date Prepared: 11 December 2019

2. Device

Trade Name: LUX-Dx™ 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: Reveal LINQ Insertable Cardiac Monitor
Manufacturer: Medtronic Inc
Clearance Number: K132649, 14 February 2014
Common Name: Arrythmia detector and alarm
Product Code/Panel: DSI, 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 ECG (S-ECG) for the clinical evaluation and diagnosis of cardiac arrhythmias. The LUX-Dx is indicated for use in patients that have a known heart condition, are at risk of developing an abnormal heart rhythm, or have symptoms that may suggest a heart condition 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 ICM sensor device (Model M301) evaluates 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 device is inserted into the subcutaneous layer of the fourth intercostal space of the left chest wall. The sensor device is powered by an integrated battery. The electrodes used for detecting the S-ECG signal are located on each end of the sensor device, in the header and at the base of the battery. The LUX-Dx system includes the following main components:

- LUX-Dx™ sensor device - a subcutaneously-implanted sensor device for cardiac arrhythmia event data collection and transmission. In addition, symptom events are collected and transmitted from the sensor 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 LUX-Dx sensor device (using Bluetooth Low Energy (BLE)) and the LATITUDE 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 sensor device, an insertion tool and incision tool are provided. In addition, a magnet is provided to initiate sensor/MM app communication.

6. Substantial Equivalence

Characteristic	BSC Model M301 LUX-Dx ICM	Medtronic Reveal LINQ LNQII
Indications for use	The LUX-Dx™ Insertable Cardiac Monitor (ICM) is intended to monitor and record subcutaneous ECG (S-ECG) for the clinical evaluation and diagnosis of cardiac arrhythmias. The LUX-Dx is indicated for use in patients that have a known heart condition, are at risk of developing an abnormal heart rhythm, or have symptoms that may suggest a heart condition such as dizziness, palpitations, syncope, chest pain, and/or shortness of breath.	The Reveal LINQ ICM is an insertable automatically-activated and patient-activated monitoring system that records subcutaneous ECG and is indicated in the following cases: • patients with clinical syndromes or situations at increased risk of cardiac arrhythmias • patients who experience transient symptoms such as dizziness, palpitation, syncope, and chest pain that may suggest a cardiac arrhythmia
Usage	Single use	Single use
Sterility	Supplied sterile	Supplied sterile
Volume Dimension	1.2 cc	1.2 cc
MR Conditional	1.5 T and 3T	1.5 T and 3T
Energy Source	Battery powered - $LiMnO_2$	Battery powered - LiCFx

Characteristic	BSC Model M301 LUX-Dx ICM	Medtronic Reveal LINQ LNQII
Longevity	3 years	3 years
Remote Monitoring	Yes	Yes
Packaging	Sterile kit including ICM device and custom implant tools. Accessories: External, non-sterile devices are packaged separately.	Sterile kit including ICM device and custom implant tools. Accessories: External, non-sterile devices are packaged separately.

7. 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 is substantially equivalent to the predicate device. The system conforms to user needs and intended use.

Performance Testing - Bench:

- Sterilization
- Biocompatibility
- Electromagnetic compatibility
- Electrical safety
- MRI compatibility
- Mechanical verification
- Implant tool verification
- Packaging Verification
- Software Verification
- Algorithm Validation
- Human Factors/Usability Testing

Performance Testing – Pre-clinical:

- LUX-Dx GLP and non-GLP studies

8. Conclusion

Based on the intended use, fundamental technological characteristics, and performance testing, the proposed LUX-Dx system has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the predicate device.