October 18, 2019

Abbott
Laura Sparks
Senior Regulatory Affairs Specialist
15900 Valley View Ct.
Sylmar, California 91342

Re: K192593
Trade/Device Name: Confirm Rx 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: DSI, MXC
Dated: September 19, 2019
Received: September 20, 2019

Dear Laura Sparks:

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 Nicole Goodsell
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)*

Device Name
Confirm Rx™ Insertable Cardiac Monitor (ICM) (DM3500)

Indications for Use *(Describe)*
The Confirm Rx™ ICM is indicated for the monitoring and diagnostic evaluation of patients who experience unexplained symptoms such as: dizziness, palpitations, chest pain, syncope, and shortness of breath, as well as patients who are at risk for cardiac arrhythmias. It is also indicated for patients who have been previously diagnosed with atrial fibrillation or who are susceptible to developing atrial fibrillation.

The Confirm Rx ICM has not been specifically tested 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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

SECTION 6
510(k) SUMMARY (CONT.)

Date Prepared:	September 18, 2019	
Submitter:	Abbott (formerly St. Jude Medical), Cardiac Rhythm Management Division	
Address:	15900 Valley View Ct. Sylmar, CA 91342 USA	
Phone:	(818) 362-6822	
Establishment Registration:	2017865	
Contact Person:	Laura Sparks Senior Regulatory Affairs Specialist (818) 493-2734 laura.sparks@abbott.com	Jennifer Dunham Manager, Regulatory Affairs (818) 493-2363 jennifer.dunham@abbott.com
Trade Name/Proprietary Name:	Confirm Rx™ ICM	
Model Number:	DM3500	
Classification Name:	Telephone electrocardiograph transmitter and receiver (21 CFR 870.2920)	
Product Code:	MXC, DSI	
Classification:	Class II	
Pediatric Use:	The Confirm Rx™ ICM has not been specifically tested in pediatric patients below the age of 18 years.	

LEGALLY MARKETED DEVICES TO WHICH SUBSTANTIAL EQUIVALENCE IS CLAIMED

510(k) K190295: Confirm Rx™ Insertable Cardiac Monitor (ICM) System

INDICATIONS FOR USE

The are no changes to the Indications for Use as a result of this submission. The Indications for Use for the Confirm Rx™ system are as follows:

> The Confirm Rx™ ICM is indicated for the monitoring and diagnostic evaluation of patients who experience unexplained symptoms such as: dizziness, palpitations, chest pain, syncope, and shortness of breath, as well as patients who are at risk for cardiac arrhythmias. It is also indicated for patients who have been previously diagnosed with atrial fibrillation or who are susceptible to developing atrial fibrillation.
>
> The Confirm Rx ICM has not been specifically tested for pediatric use.

SECTION 6
510(k) SUMMARY (CONT.)

PRODUCT DESCRIPTION

The device description of the Confirm Rx™ Insertable Cardiac Monitor (ICM) Model DM3500 is as follows:

- **Confirm Rx™ ICM Model DM3500 Implantable Device**: The ICM is intended as a minimally invasive, implantable diagnostic monitoring device, with subcutaneous electrodes, looping memory, and automatic as well as patient-activated EGM storage capability, which help physicians monitor, diagnose, and document patients who are susceptible to cardiac arrhythmias. It has a two-year longevity, MR conditional labeling, sensing and detection algorithms, and Bluetooth communication. Specific features include:
  - Patient-initiated triggering of EGM storage using the myMerlin™ Patient App for mobile devices. This includes capability for the patient to identify symptoms, which are stored with the EGM for physician review.
  - Automated triggering of EGM storage when tachycardia, bradycardia, or pauses are detected; with physician-programmable values for pause duration, bradycardia rate, tachycardia rate, and number of tachycardia intervals.
  - Automated triggering of EGM storage when atrial fibrillation (AF) is detected, with physician programmable values for AF duration.
  - The ability to identify EGM anomalies as a consequence of noise or vigorous activity and inhibit EGM storage as applicable.
  - Remote care monitoring.

- **Implant Tools: Model DM3520** incision tool and **Model DM3510** insertion tool to implant the device subcutaneously. The implantable device is pre-loaded into the insertion tool and packaged together with the incision tool.
  - The DM3520 incision tool is used to make an angled cut, which is the sole incision required to implant the ICM. The introducer end of the DM3510 insertion tool is inserted, creating the initial pocket (Figure 1).
  - With the insertion tool in place, the plunger is withdrawn to drop the pre-loaded device into the insertion channel. The plunger is pushed forward to insert the device into the pocket (Figure 1). This completes insertion (implantation) of the ICM, and the incision is closed per standard of care.

SECTION 6
510(k) SUMMARY (CONT.)

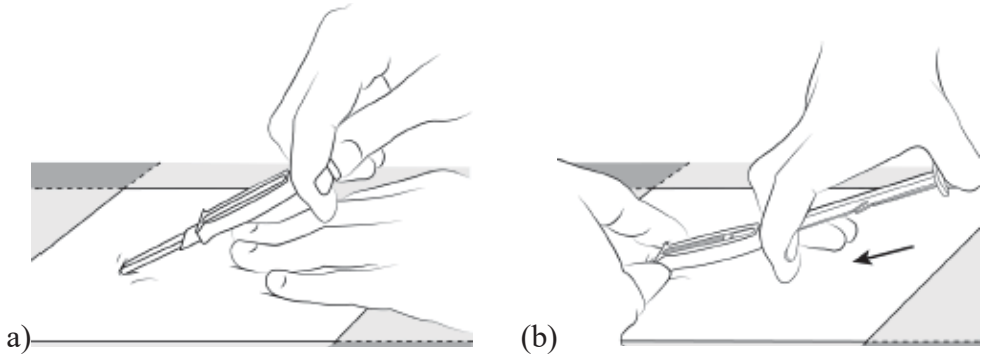

Figure 1: Insertion Process

- **Model 3111 Magnet** (existing SJM donut magnet) facilitates faster startup of Bluetooth connection and provides user authentication (required for programmer sessions).
- **Clinician Programmer (Merlin PCS Programmer Model 3650)**: The Merlin PCS Programmer 3650 operates using Merlin PCS Model 3330 software and provides the means for the physician to program device parameters and retrieve diagnostic information from the device, including electrograms, heart rate history, episode duration and trend information. The Merlin PCS programmer, using the Model BLU1000 Bluetooth dongle, an off the shelf component, communicates with the Confirm Rx™ device with Bluetooth telemetry (also referred to as Bluetooth Low Energy or BLE). Programmer software Model 3330 v23.0.1 and later will contain support for the Confirm Rx™ device, adding support for the Model BLU1000 Bluetooth dongle, and new tabs of Implant View and Reason for Monitoring features.
    - **Implant View** is designed to streamline programming at the time of implant. Upon initial interrogation at implant, the programmer automatically displays the Implant View in which the user can immediately input device and patient information to be stored onto the device, as well as set the Reason for Monitoring.
    - **Reason for Monitoring** allows the user to select from a list of possible conditions for which the patient is receiving the device (such as Syncope, Ventricular Tachycardia, Palpations, etc). The programmer then sets the AF duration parameter and EGM storage priority based on the reason selected. These parameters can be manually adjusted by the user later, if customization is preferred.
- **myMerlin™ Patient App** (Model APP1000 Android): The Patient App provides the means for the patient to activate EGM recording in the Confirm Rx™ device, with data pass-through functionality to enable physician follow-up via the Merlin.net Patient Care Network. Patients who do not supply their own mobile device will be provided a Model MTX1000 mobile device. The MTX1000 is an off-the-shelf unit, a Samsung J3, and is not part of the medical device.
- **Remote Care/Clinician Portal** (Merlin.net MN5000 Report Generator): The Merlin.net MN5000 system allows physicians to remotely monitor and diagnose patients' cardiac events. The Merlin.net MN5000 v7.5 contains updates that are specific to Confirm Rx™.

SECTION 6
510(k) SUMMARY (CONT.)

TECHNOLOGICAL CHARACTERISTICS

The Confirm Rx™ ICM (DM3500) is 4.95 x 0.95 x 0.33 cm in dimension and uses Bluetooth® wireless telemetry to communicate with external devices, including the Merlin PCS programmer and the myMerlin™ mobile application. The remote monitoring equipment for the Confirm Rx™ ICM is the myMerlin™ mobile application, installed on a patient's or Abbott-provided mobile device, using built-in cellular and Wi-Fi connectivity. The Confirm Rx™ ICM (DM3500) will continue to use the same technology.

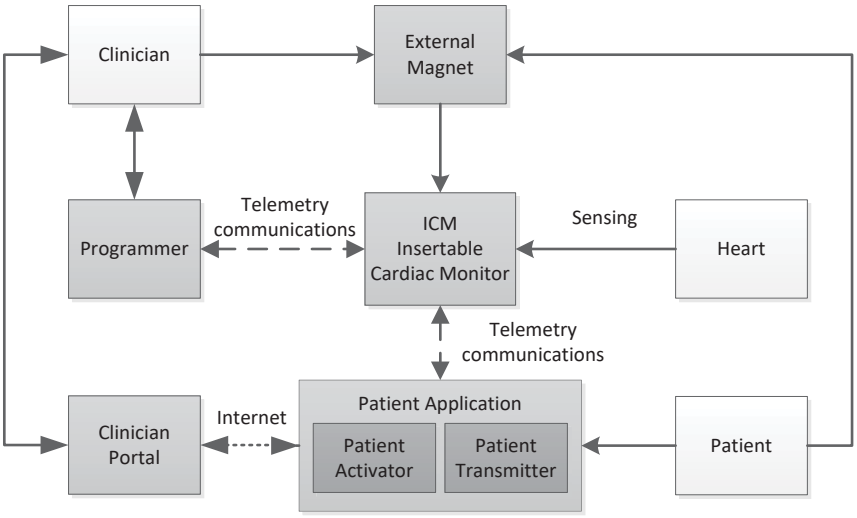

Figure 2: Block Diagram of Confirm Rx™ ICM System

Only the Confirm Rx™ ICM DM3500 is the subject of this premarket notification. The Merlin PCS 3650 programmer and Merlin.net MN5000 are already FDA approved, with Confirm Rx™ supported on programmer software model 3330 v23.0.1 or higher (per P910023/S382 approved on October 20, 2017) and on Merlin.net v7.5 or higher (per P910023/S381 approved on October 20, 2017). The myMerlin™ for Confirm Rx™ mobile applications are FDA cleared per 510(k) K163407 on September 29, 2017 (Android app, APP1000) and K173232 on November 2, 2017 (iOS app, APP1001). The magnet, Model 3111, is Class I exempt MDDS.

The Confirm Rx™ ICM (both predicate (K190295) and candidate) is MR Conditional.

The Confirm Rx™ ICM is encased in parylene-coated titanium that incorporates two subcutaneous electrodes. The header material on the Confirm Rx™ ICM is molded thermoplastic polyurethane (TPU). The battery chemistry of the Confirm Rx™ device is lithium carbon monofluoride.

The fundamental technological characteristics of the Confirm Rx™ ICM are not changing. In comparison to the predicate device, the current Confirm Rx™ ICM DM3500 (cleared on April

SECTION 6
510(k) SUMMARY (CONT.)

10, 2019 per 510(k) K190295), the candidate Confirm Rx™ ICM DM3500 with peel and stick moisture getter has the same:

- Intended Use and Indications for Use
- Operating rules
- Device functionality
- Packaging materials and process
- Shelf life
- Device Longevity

In comparison to the predicate device, the current Confirm Rx™ ICM DM3500 (cleared on April 10, 2019 per 510(k) K190295), the candidate Confirm Rx™ ICM DM3500 with peel and stick moisture getter has the following differences:

- The candidate Confirm Rx™ ICM with peel and stick moisture getter contains minor design changes in the moisture getter's location and area of contact with internal device components:
    - Moisture getter is located on the hybrid
    - Adhesive backing is in contact with the hybrid

NON-CLINICAL TEST SUMMARY

The risk analysis method used to assess the impact of the peel and stick moisture getter documents the investigation of hazards and mitigation of associated risks and reports the result of the investigation. The risk analysis method used to assess the impact of the modifications was a Failure Mode and Effects Analysis (FMEA/FMECA). It was determined that the overall risk is acceptable. Completion of all verification and validation activities demonstrated that the device with the peel and stick moisture getter material meets its predetermined design and performance specifications and that the product is substantially equivalent to the current device (Model DM3500, K190295).

CONCLUSION (SUBSTANTIAL EQUIVALENCE)

The results of the verification and validation tests and the risk analysis have demonstrated the Confirm Rx™ ICM DM3500 with peel and stick moisture getter functions in accordance with product specifications. The candidate Confirm Rx™ ICM DM3500 is substantially equivalent in terms of safety and technological characteristics to the identified predicate device. Product verification and validation testing demonstrate that the Confirm Rx™ ICM is as safe and as effective and performs as well as the predicate device. The indications for use are not impacted by the peel and stick moisture getter. The fundamental scientific technology of the Confirm Rx™ ICM DM3500 remains unchanged. Thus, the candidate Confirm Rx™ ICM DM3500 with peel and stick moisture getter is deemed to be substantially equivalent to the predicate Confirm Rx™ ICM DM3500 cleared on April 10, 2019 per 510(k) K190295.