March 17, 2020

Abbott (St. Jude Medical)
Vanessa Powell
Regulatory Affairs Specialist
15900 Valley View Court
Sylmar, California 91342

Re: K193310
Trade/Device Name: myMerlin Mobile Application (Android), myMerlin Mobile Application (iOS)
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: Class II
Product Code: MXC, DSI
Dated: March 11, 2020
Received: March 12, 2020

Dear Vanessa Powell:

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,

Jennifer Shih
Assistant Director (Acting)
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 System

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

510(k) SUMMARY

Date Prepared:	November 27, 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:	Vanessa Powell Regulatory Affairs Specialist (818) 493-3290 vanessa.powell@abbott.com Jennifer Dunham Manager, Regulatory Affairs (818) 383-1630 jennifer.dunham@abbott.com
Trade Name/Proprietary	Confirm Rx™ Insertable Cardiac Monitor System
Common Name:	Insertable Cardiac Monitor
Model Number:	DM3500 (including APP1000 (Android) and APP1001 (iOS))
Classification Name:	Telephone electrocardiograph transmitter and receiver (21 CFR 870.2920)
Product Code:	MXC, DSI
Classification:	Class II
Pediatric Use:	The Confirm Rx™ Insertable Cardiac Monitor 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) K192593 Confirm Rx™ Insertable Cardiac Monitor System

INDICATIONS FOR USE

There are no changes to the Indications for Use as a result of this submission. The Indications for Use for the Confirm Rx™ Insertable Cardiac Monitor (ICM) 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.

510(k) SUMMARY

PRODUCT DESCRIPTION

The Abbott Confirm Rx™ (ICM) System consists of the following key features and components:

- **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. Specific features include:
  - Patient-initiated triggering of EGM storage using the myMerlin™ mobile application. 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.
  - The addition of remote care capabilities
- **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.

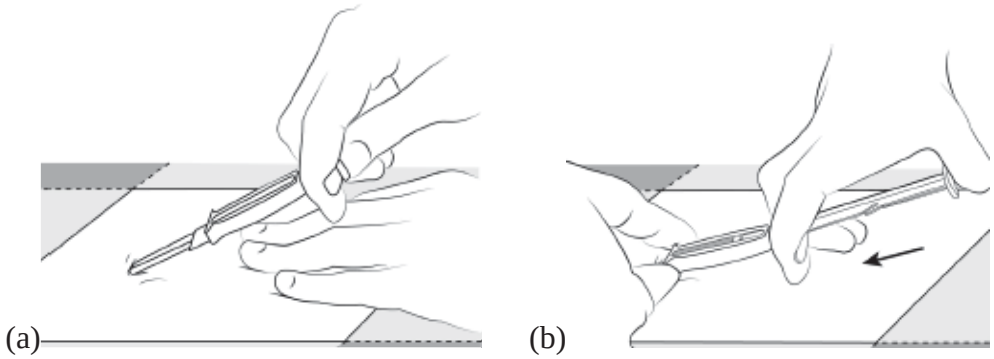

Figure 1: Insertion Process

510(k) SUMMARY

- **Model 3111 Magnet**: 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) and APP1001 (iOS)): The mobile application 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 may be provided with an Abbott issued off the shelf Android mobile device, which is not a 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 v7.7 contains updates that are specific to Confirm Rx™.

510(k) SUMMARY

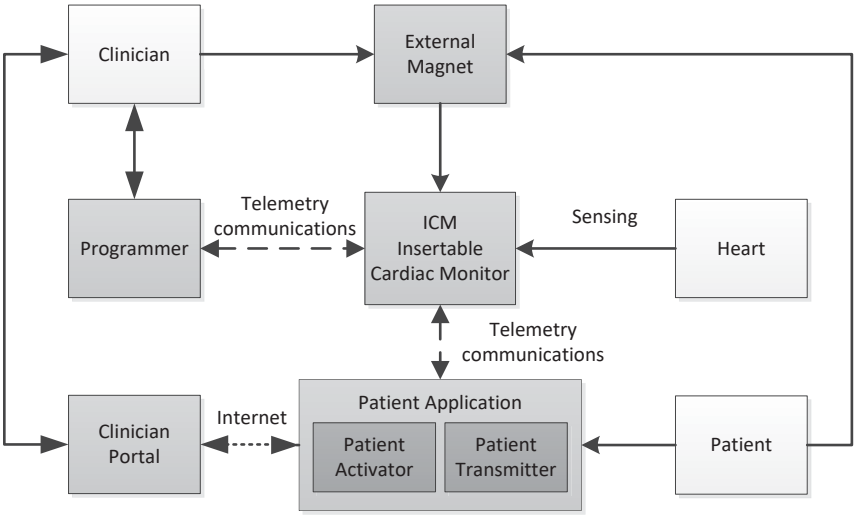

Figure 2: Block Diagram of Confirm Rx™ ICM System

The myMerlin™ mobile application, APP1000 and APP1001, are the subject of this premarket notification for the Confirm Rx™ ICM System. The Confirm Rx™ ICM device Model DM3500 was cleared on October 18, 2019 per 510(k) K192593. The Confirm Rx™ ICM, DM3500, Implant Tools, Model DM3520 and DM3510 are not the subject of this premarket notification. The Merlin PCS programmer, Model 3330 v24.5.1 software for the Model 3650 Merlin PCS programmer and Merlin.net MN5000 v7.7 are not subject of this premarket notification. The magnet, Model 3111, is Class I exempt MDDS and not subject of this premarket notification.

TECHNOLOGICAL CHARACTERISTICS

The fundamental technological characteristics of the myMerlin™ mobile application Model APP1000 and APP1001 are the same as the predicate myMerlin™ mobile application Model APP1000 (Android) and APP1001 (iOS). Model APP1000 runs on the Android operating system and Model APP1001 runs on the iOS operating system. The myMerlin™ for Confirm Rx™ mobile application provides the means for the patient to activate EGM recording in the Confirm Rx™ ICM device, with data pass-through functionality to enable physician follow-up via theMerlin.net Patient Care Network (clinician portal). The Confirm Rx™ ICM (DM3500) will continue to use the same technology. See **Figure 2** for a block diagram of the Confirm Rx™ ICM system.

The myMerlin™ mobile application provides the means for the patient to activate EGM recording in the Confirm Rx™ ICM device, with data pass-through functionality to enable physician follow-up via the Merlin.net Patient Care Network (clinician portal). The Confirm Rx™ ICM (DM3500) will continue to use the same technology.

The fundamental technological characteristics of the myMerlin™ mobile application are not changing. In comparison to the predicate device the myMerlin™ mobile application and the

510(k) SUMMARY

candidate Confirm Rx™ ICM system with the updated myMerlin™ mobile application with updated mobile application have the same:

- Intended Use and Indications for Use
- Operating rules
- Cybersecurity
- Usability Testing

SUBSTANTIAL EQUIVALENCE

The Confirm Rx™ ICM System, including the myMerlin™ mobile application with the proposed updates and enhancements, is substantially equivalent to the predicate Confirm Rx™ ICM System (K192593, cleared on October 18, 2019). The indications for use are not impacted by the updated mobile application operations. Both the candidate and the predicate device (APP1000 Android, and APP1001 iOS) have the same function and fundamental scientific technology. The minor differences do not raise new issues of safety and effectiveness. Thus, the candidate Confirm Rx™ ICM System, including the updated myMerlin™ mobile application Model APP1000 and APP1001, is substantially equivalent to the predicate Confirm Rx™ ICM System (K192593).

In comparison to the predicate myMerlin™ mobile application, the candidate myMerlin™ mobile application has the following differences:

- The candidate myMerlin™ mobile application with updated telemonitoring communication contains the following changes:
    - Update to improve myMerlin™ mobile application scheduled background workflows
    - Update of the telemetry connectivity of the Confirm Rx™ ICM System including the myMerlin™ mobile application and Confirm Rx™ ICM device.
- The candidate myMerlin™ mobile application, model APP1000, is being updated to allow the patient's remote monitoring support profile on Merlin.net to be transferred from the implant clinic to the remote monitoring clinic.

TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

All necessary testing was conducted on the candidate myMerlin™ mobile application to support a determination of substantial equivalence to the predicate device, including:

- Software Verification and System Verification
- Design Validation
- Bluetooth Low Energy Proxy Software Verification

Completion of all verification and validation activities demonstrated that the updated mobile application meets its predetermined design and performance specifications and that the product is substantially equivalent to the predicate myMerlin™ mobile application, model APP1000 (Android) and APP1001(iOS). The results of the testing show that the candidate Confirm Rx™ ICM System with updated myMerlin™ mobile application performs as intended and is safe for its intended use.

510(k) SUMMARY

CONCLUSION

The myMerlin™ mobile application is used in conjunction with the Confirm Rx Insertable Cardiac Monitor (ICM) System; therefore, the indications for use are not impacted by the updates and enhancements to the myMerlin mobile application. The results of the verification and validation tests and the risk analysis have demonstrated the myMerlin™ mobile application within the Confirm Rx™ ICM System functions in accordance with the product specifications.