November 23, 2020

Abbott (St. Jude Medical)
Laura Sparks
Sr. Regulatory Affairs Specialist
15900 Valley View Ct.
Sylmar, California 91342

Re: K202888
Trade/Device Name: Confirm Rx Insertable Cardiac Monitor
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: Class II
Product Code: MXC, DSI
Dated: September 25, 2020
Received: September 28, 2020

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,

Jennifer Shih
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)*
K202888

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.

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K202888
510(k) SUMMARY

Date Prepared:	September 25, 2020	
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 Sr. Manager, Regulatory Affairs (818) 383-1630 jennifer.dunham@abbott.com
Trade Name/Proprietary	Confirm Rx™ Insertable Cardiac Monitor	
Common Name:	Insertable Cardiac Monitor	
Model Number:	DM3500	
Classification Name:	21 CFR 870.2800, Medical magnetic tape recorder	
Product Code:	MXC, DSI	
Classification:	Class II	
Pediatric Use:	The Confirm Rx™ Insertable Cardiac Monitor has not been specifically tested in pediatric patients.	

LEGALLY MARKETED DEVICES TO WHICH SUBSTANTIAL EQUIVALENCE IS CLAIMED

510(k) K193310 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.

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510(k) SUMMARY (CONT.)

PRODUCT DESCRIPTION

The 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.
  - Remote monitoring capabilities
- **Implant Tools: Model DM3520** incision tool and **Model DM3510** insertion tool are used 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 to the skin during the insertion procedure. The blunt dissection tip of the insertion of the DM3510 insertion tool is inserted just past the skin creating a subcutaneous pocket parallel to the skin (**Figure 1, a)**.
  - With the insertion tool advanced as far as it can go, until the flared edge contacts the incision site. The plunger is withdrawn until the plunger stops and the preloaded device drops completely into the insertion channel. The plunger is advanced to insert the device into the subcutaneous pocket (**Figure 1, b**). The plunger has a feature to stop the introducer when the device is at the proper depth. This completes insertion (implantation) of the ICM, and the incision is closed per standard of care.

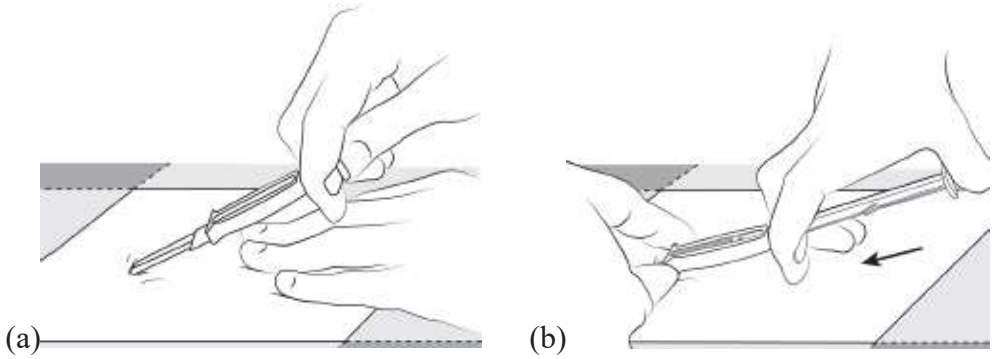

Figure 1: Insertion Process

- **Magnet**: The 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 Bluetooth dongle, an MDDS component, communicates with the Confirm Rx™ device with Bluetooth telemetry (also referred to as Bluetooth Low Energy or Bluetooth LE). Programmer software Model 3330 v23.0.1 and later contains support for the Confirm Rx™ device and the Bluetooth dongle as well as tabs within the user interface for 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™ Mobile Application** (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 system allows physicians to remotely monitor and diagnose patients' cardiac events. The Merlin.net MN5000 v7.5 software and later contains support for the Confirm Rx™ device.

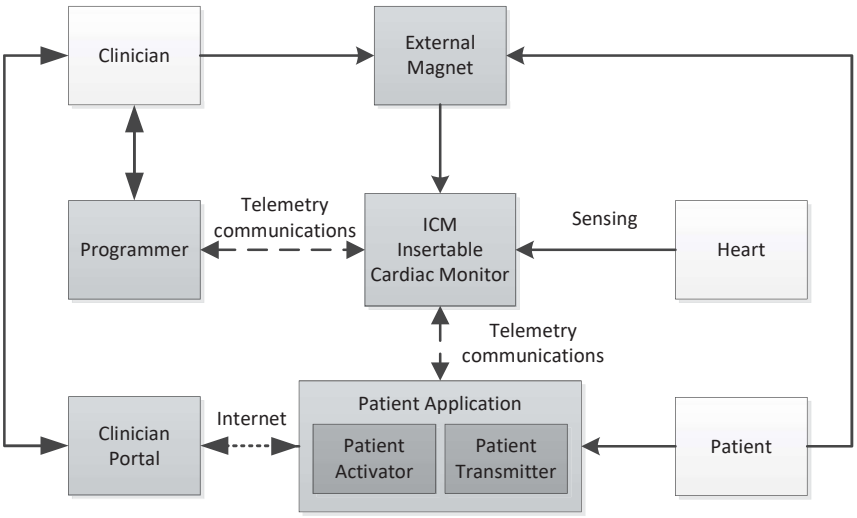

Figure 2: Block Diagram of Confirm Rx™ ICM System

TECHNOLOGICAL CHARACTERISTICS

The Confirm Rx™ ICM (DM3500) is 49 x 9.4 x 3.1 mm in dimension and uses Bluetooth® wireless telemetry to communicate with external devices, including the Merlin PCS programmer and the myMerlin™ mobile application. An external magnet facilitates faster startup of Bluetooth connection and provides user authentication (required for programmer sessions). 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 or Wi-Fi connectivity. 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. See **Figure 2** for a block diagram of the Confirm Rx™ ICM system.

The subject of this premarket notification is the Confirm Rx™ ICM DM3500 with updated MR Conditional labeling. There are no changes to the predicate (K193310) Confirm Rx™ Insertable Cardiac Monitor DM3500, the incision tool DM3520 or insertion tool DM3510, or the myMerlin™ mobile applications within the scope 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 magnet is Class I exempt MDDS.

The Confirm Rx™ ICM (both predicate (K193310) and candidate) is MR Conditional for scans in a 1.5T MRI environment. The testing performed supports additional 3T MR Conditional labeling.

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510(k) SUMMARY (CONT.)

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 technology of the Confirm Rx™ ICM are not changing. In comparison to the predicate device, the Confirm Rx™ ICM DM3500 (510(k) K193310), the candidate Confirm Rx™ ICM DM3500 with added 3T MR Conditional labeling has the same:

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

In comparison to the predicate Confirm Rx™ ICM device (K193310), the candidate Confirm Rx™ ICM DM3500 with 3T MR Conditional labeling has the following differences:

- The candidate Confirm Rx™ ICM with updated MR Conditional labeling allows for MRI scans in a 3T scanning environment.

SUBSTANTIAL EQUIVALENCE

The Confirm Rx™ ICM with updated MR Conditional labeling is substantially equivalent to the predicate Confirm Rx™ ICM DM3500 (K193310). The indications for use are not impacted by the updated MR Conditional labeling for use in a 3T MRI scanning environment. Both the candidate and the predicate device (K193310) have the same function and fundamental technology. The updated labeling does not raise new issues of safety and effectiveness. The performed 3T testing meets the same clinical acceptance criteria that was previously evaluated for predicate 1.5T MR Conditional labeling demonstration of safety. Thus, the candidate Confirm Rx™ ICM (DM3500) with the addition of 3T MR Conditional labeling is substantially equivalent to the predicate Confirm Rx™ ICM (DM3500) (K193310).

TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

All necessary device and system verification testing conducted on the candidate Confirm Rx™ ICM DM3500 supports a determination of substantial equivalence to the predicate device.

Completion of all verification activities demonstrated the device with updated MR Conditional labeling meets its predetermined design and performance specifications and that the product is substantially equivalent to the predicate Confirm Rx™ ICM device (K193310). The results of

K202888
510(k) SUMMARY (CONT.)

the testing show that the candidate Confirm Rx™ ICM performs as intended and is safe for its intended use.

CONCLUSION

The Confirm Rx™ ICM is an implantable cardiovascular monitoring device, for which the candidate device shares its design and mechanism of action, as well as the indications for use, with the identified predicate Confirm Rx™ ICM (K193310). The results of the MRI verification testing have demonstrated the candidate Confirm Rx™ ICM DM3500 with updated MR Conditional labeling functions in accordance with product specifications. The fundamental technology of the Confirm Rx™ ICM DM3500 remains unchanged. The candidate Confirm Rx™ ICM with the addition of 3T MR Conditional labeling is substantially equivalent to the predicate Confirm Rx™ ICM (K193310) in terms of technology, intended use, and performance.