December 1, 2020

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

Re: K202876
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: October 30, 2020
Received: November 2, 2020

Dear Juni Sarkar:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202876

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 the following: 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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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	
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Establishment Registration:	2017865	
Contact Person:	Juni Sarkar Senior Regulatory Affairs Specialist (818) 294-3429 juni.sarkar@abbott.com	Jennifer Dunham Sr. Manager, Regulatory Affairs (818) 383-1630 jennifer.dunham@abbott.com
Trade Name/Proprietary Name:	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

The 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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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:** Incision tool (**model DM3520; Figure 1, a**) and Insertion tool (**model DM3510; Figure 1, b**) 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 blade on the candidate incision tool DM3520 within this premarket notification has been updated as compared to the predicate (K193310).
  - The blunt dissection tip of the DM3510 insertion tool is inserted just past the skin creating a subcutaneous pocket parallel to the skin (**Figure 2, a**). With the insertion tool in place as far as it can go, until the flared edge contacts the incision site, the plunger is withdrawn to drop the pre-loaded device into the insertion channel. The plunger is advanced to insert the device into the subcutaneous pocket (**Figure 2, b**). This completes insertion (implantation) of the ICM, and the incision is closed per standard of care.

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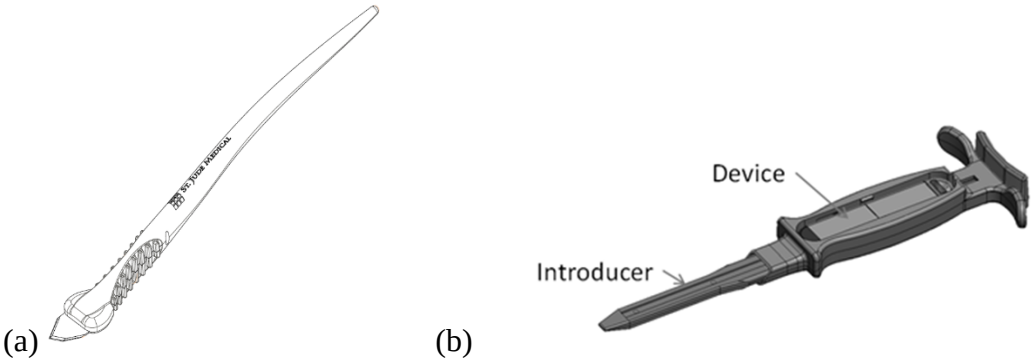

Figure 1: Implant tools

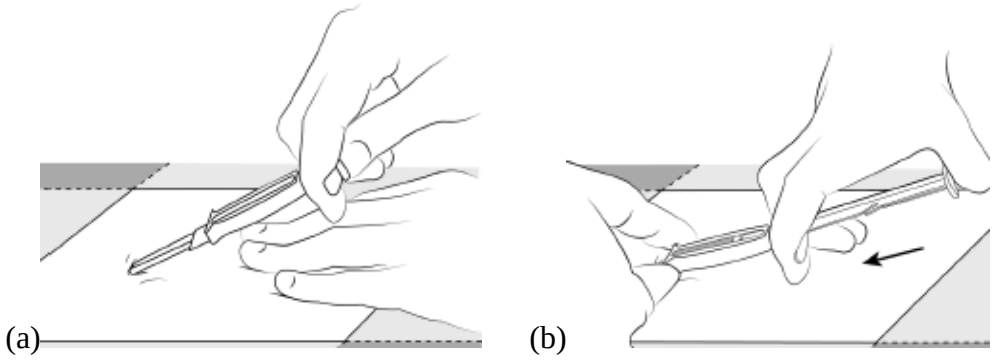

Figure 2: Insertion Process

- **Confirm Rx ICM Accessory Kit DM3500A:** The Confirm Rx™ ICM Accessory Kit Model DM3500A is a sterilized, standalone, one-time use convenience kit containing the Confirm Rx™ ICM Insertion Tool DM3510 and the Confirm Rx™ ICM Incision Tool DM3520. The implant tools are manufactured, packaged and sterilized identically to the DM3500 Confirm Rx ICM, however, the candidate Confirm Rx™ ICM system will allow for availability of the implant tools separately in a convenience kit, without the pre-loaded Confirm Rx ICM in the insertion tool.

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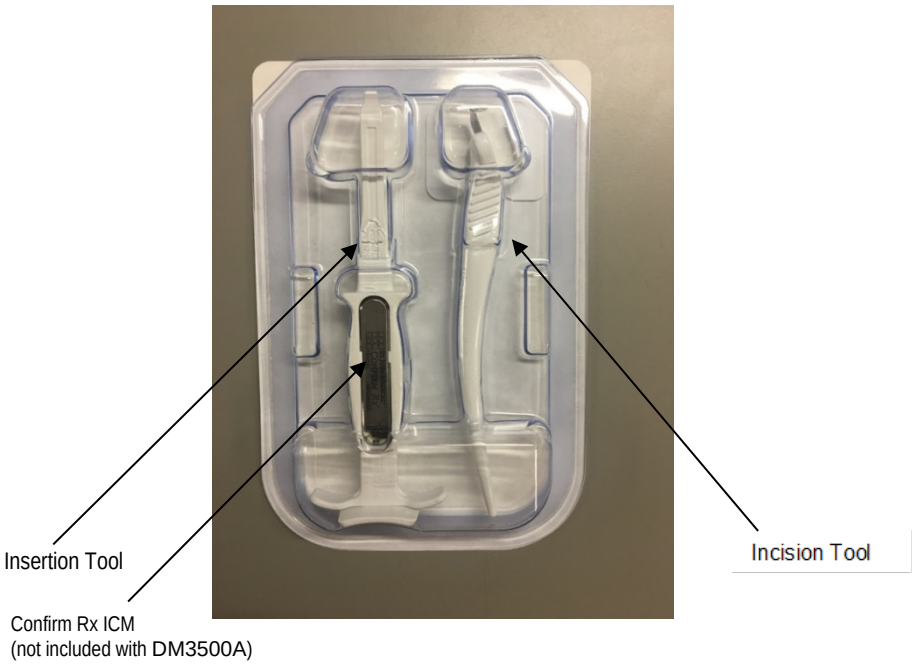

Figure 3: Confirm Rx ICM DM3500 and Accessories in the Sterile Packaging; Annotated to Reflect DM3500A

- **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 a 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 a 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.

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- **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 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.

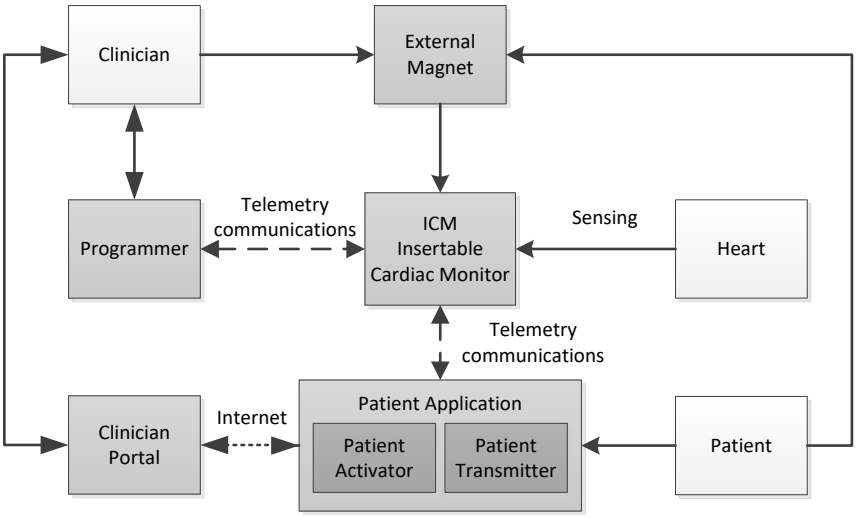

Figure 4: Block Diagram of Confirm Rx™ ICM System

TECHNOLOGICAL CHARACTERISTICS

The Confirm Rx™ ICM (DM3500) is 49 x 94 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 Confirm Rx™ ICM (DM3500) will continue to use the same technology. 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 4** for a block diagram of the Confirm Rx™ ICM system.

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The subject of this premarket notification is the Confirm Rx™ ICM DM3500 system with Accessory Kit DM3500A and updated incision tool DM3520 blade design. There are no changes to the predicate (K193310) Confirm Rx™ Insertable Cardiac Monitor DM3500, the 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 Accessory Kit Model DM3500A is a sterilized, standalone, one-time use convenience kit containing the Confirm Rx™ ICM Insertion Tool DM3510 and the Confirm Rx™ ICM Incision Tool DM3520. The implant tools are manufactured, packaged and sterilized identically to the predicate (K193310) Confirm Rx ICM DM3500 system; however, the candidate Confirm Rx™ ICM system will allow for availability of the implant tools separately in a convenience kit, without the pre-loaded Confirm Rx ICM in the insertion tool that is shown in the **Figure 3**.

Additionally, the incision tool DM3520 blades in traditional ICM cutting tools such as in the predicate (K193310) Confirm Rx™ ICM system have a V-shape (2 edge) design to achieve the desired width and depth for the cut. The proposed blade design for the incision tool in the candidate Confirm Rx™ ICM system is a 3-Edged Blade. The Incision tool DM3520 blade design has been modified as an improvement to further sharpen and strengthen only the leading edge of the blade using a honing process and will be packaged with both the Confirm Rx ICM Accessory Kit DM3500A and the Confirm Rx ICM DM3500.

The fundamental technological characteristics of the Confirm Rx™ ICM DM3500 and the implant tools DM3510 and DM3520 are not changing. In comparison to the predicate device, the current Confirm Rx™ ICM DM3500 (510(k) K193310), the candidate Confirm Rx™ ICM system has the same:

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

NON-CLINICAL TEST SUMMARY

The risk analysis method used to assess the impact of the addition of the Confirm Rx ICM Accessory Kit and the incision tool blade design change 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 Confirm Rx ICM accessory kit meets

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its predetermined design and performance specifications and that the product is substantially equivalent to the current device (Model DM3500, K193310).

SUBSTANTIAL EQUIVALENCE

The candidate Confirm Rx™ ICM system includes an Accessory Kit DM3500A and an updated incision tool DM3520 blade design. The design of the Confirm Rx ICM Accessory Kit DM3500A packaging (candidate) is identical to the Confirm Rx ICM DM3500 packaging (predicate device; K193310), except that the DM3500A package does not include the Confirm Rx ICM (as shown in **Figure 3**). In addition, the incision tool DM3520 blade design has been updated which will be packaged both in the new Confirm Rx™ ICM accessory kit DM3500A and in the existing Confirm Rx™ ICM DM3500 package with the Confirm Rx™ ICM device. The blade material is unchanged. The same indications that are listed in the Confirm Rx™ ICM instructions for use apply to both the candidate and predicate (K193310) Confirm Rx ICM DM3500 system. The indications for use are not impacted by the proposed design change. Both the candidate and the predicate device (K193310) have the same function and fundamental scientific technology. The minor differences in the package contents and incision tool blade design do not raise new questions of safety and effectiveness. Thus, the candidate Confirm Rx™ ICM system with Accessory Kit DM3500A and the updated incision tool DM3520 blade design is substantially equivalent to the predicate Confirm Rx™ ICM DM3500 system (K193310).

TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

All necessary device and system verification testing conducted on the candidate Confirm Rx ICM System with Accessory Kit DM3500A and the updated incision tool DM3520 blade design supports a determination of substantial equivalence to the predicate device.

Completion of all verification activities demonstrated the device 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 the testing show that the candidate Confirm Rx ICM system performs as intended and is safe for its intended use.

CONCLUSION (SUBSTANTIAL EQUIVALENCE)

The results of the verification and validation tests and the risk analysis have demonstrated the candidate Confirm Rx ICM system with Accessory Kit DM3500A and updated incision tool DM3520 blade design functions in accordance with product specifications. The candidate Confirm Rx ICM system is substantially equivalent in terms of safety and technological characteristics to the identified predicate device (Confirm Rx™ ICM System; K193310). Product verification and validation testing demonstrate that the candidate Confirm Rx ICM system is as safe and as effective and performs as well as the predicate system (K193310). The indications for use are not impacted by new Confirm Rx ICM Accessory Kit and the design update to incision tool DM3520 blade. The fundamental scientific technology of the Confirm Rx™ ICM DM3500 system remains unchanged. Thus, the candidate Confirm Rx ICM System with Accessory Kit DM3500A and updated incision tool DM3520 blade design is deemed to be substantially equivalent to the predicate Confirm Rx™ ICM DM3500 cleared 510(k) K193310.