SECTION 5
510(k) SUMMARY (CONT.)

Date Prepared:	February 8, 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 Regulatory Affairs Specialist (818) 493-2734 laura.sparks@abbott.com	Jennifer Dunham Manager, Regulatory Affairs (818) 383-1630 jennifer.dunham@abbott.com
Trade Name/Proprietary Name:	Confirm Rx™ Insertable Cardiac Monitor System	
Common Name:	Insertable Cardiac Monitor	
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™ 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) K182981 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.

SECTION 5
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.

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™ for Confirm Rx™ 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™ for Confirm Rx™ mobile application, installed on a patient's or Abbott-provided mobile device, using built-in cellular or Wi-Fi connectivity. 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 the Merlin.net Patient Care Network (clinician portal). The Confirm Rx™ ICM (DM3500) will continue to use the same technology. See **Figure 1** for a block diagram of the Confirm Rx™ ICM system.

SECTION 5
510(k) SUMMARY (CONT.)

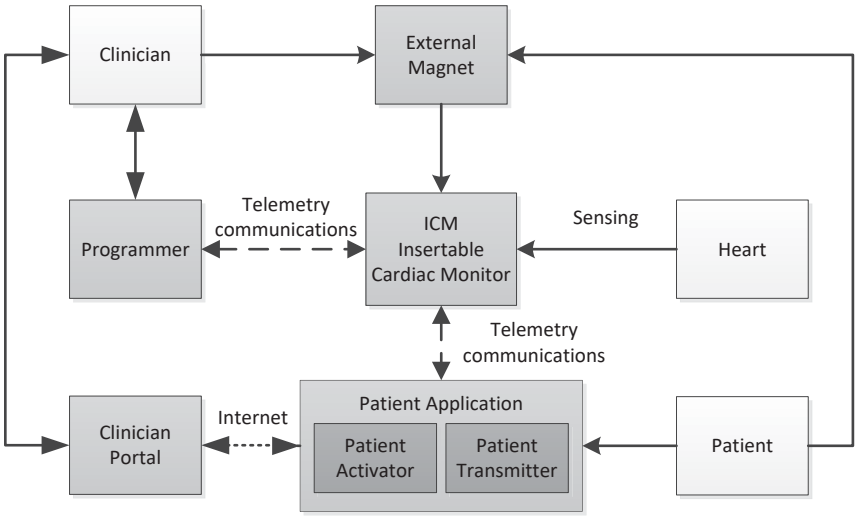

Figure 1: Block Diagram of Confirm Rx™ ICM System

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 (K182981) 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 Confirm Rx™ ICM DM3500 (K182981), the candidate Confirm Rx™ ICM DM3500 with modified FW 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 Confirm Rx™ ICM device (K182981), the candidate Confirm Rx™ ICM DM3500 with modified firmware has the following differences:

SECTION 5
510(k) SUMMARY (CONT.)

- The candidate Confirm Rx™ ICM with updated firmware contains changes pertaining to its detection algorithms for the diagnosis of bradycardia, asystole (pause), and atrial fibrillation (AF):
    - Second pass undersensing discriminators added to the Asystole and Bradycardia detection algorithms to reject false Pause and Bradycardia detections.
    - Second pass P-wave detection discriminator to reject false AF detections.

- The candidate Confirm Rx™ ICM with updated firmware also contains the following changes:
    - Accounted for the current drain and time used to execute the undersensing and P-wave discriminators within the battery longevity calculation.
    - Added a check for the presence of non-AF Electrogram Triggers within an AF Entry Post-Trigger duration.
    - Added a check if Atrial Summary Diagnostics were cleared during an ongoing AF Episode.
    - Modified the AF Episode Alert to be triggered 15 seconds after meeting the defined episode duration threshold.
    - Modified firmware to start its first periodic check of FRAM integrity on launching the Therapy Application.
    - Modified firmware to monitor duty cycle values to detect and log occurrences of duty cycle values that have a higher value and duration than the defined thresholds.
    - Modified Bluetooth Low Energy (BLE) driver firmware to add the capability to reset the Real Time (RT) EGM buffer upon buffer overflows.

SUBSTANTIAL EQUIVALENCE

The Confirm Rx™ ICM with updated firmware is substantially equivalent to the predicate Confirm Rx™ ICM DM3500 (K182981). The indications for use are not impacted by the updated firmware. Both the candidate and the predicate device (K182981) 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 (DM3500) with FW F9.3.0F is substantially equivalent to the predicate Confirm Rx™ ICM (DM3500) (K182981).

TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

All necessary testing was conducted on the candidate Confirm Rx™ ICM DM3500 to support a determination of substantial equivalence to the predicate device, including:

- Software/Firmware Verification and System Verification
- Clip Testing
- Design Validation

Completion of all verification and validation activities demonstrated that the device with updated firmware meets its predetermined design and performance specifications and that the product is substantially equivalent to the predicate Confirm Rx™ ICM device (K182981). The results of

SECTION 5
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 (K182981). The results of the verification and validation tests have demonstrated the candidate Confirm Rx™ ICM DM3500 with updated firmware functions in accordance with product specifications. The fundamental scientific technology of the Confirm Rx™ ICM DM3500 remains unchanged. The candidate Confirm Rx™ ICM with updated firmware is substantially equivalent to the predicate Confirm Rx™ ICM (K182981) in terms of technological characteristics, intended use, and performance.