DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 29, 2017

St. Jude Medical, Inc.
Jennifer Dunham
Sr. Regulatory Affairs Specialist
15900 Valley View Ct.
Sylmar, California 91342

Re: K163407
Trade/Device Name: Confirm Rx™ Insertable Cardiac Monitor (ICM) System, Model DM3500
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: Class II
Product Code: MXC
Dated: August 28, 2017
Received: August 29, 2017

Dear Jennifer Dunham:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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)*
K163407

Device Name
Confirm Rx™ Insertable Cardiac Monitor (ICM) System, Model 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.

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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."

510(k) SUMMARY K163407

Date Prepared:	December 2, 2016	
Submitter:	St. Jude Medical, Cardiac Rhythm Management Division	
Address:	15900 Valley View Ct. Sylmar, CA 91342 USA	
Phone:	(818) 362-6822	
Contact Person:	Jennifer Dunham Sr. Regulatory Affairs Specialist (818) 493-2363 jdunham02@sjm.com	Colleen Canan Sr. Regulatory Affairs Manager (818) 493 2960 ccanan@sjm.com
Trade Name/Proprietary Name:	Confirm Rx™ Insertable Cardiac Monitor (ICM) System, Model DM3500	
Common Name:	Insertable Cardiac Monitor	
Model Number:	DM3500	
Classification Name:	Medical magnetic tape recorder (21 CFR 870.2800)	
Product Code:	MXC	
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) K133481: SJM Confirm™ (Model DM2102) Implantable Cardiac Monitor
510(k) K132649: Medtronic Reveal LINQ™ (Model LNQ11) Insertable Cardiac Monitor

INDICATIONS FOR USE

The Indications for Use for the Confirm Rx™ ICM 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 St. Jude Medical Confirm Rx™ 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. It is predicated on SJM Confirm™ DM2102 with a two-year longevity, MR conditional labeling, and identical sensing and detection algorithms as SJM Confirm™ DM2102, but with downsized hardware 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.
  - The addition of remote care capabilities, previously unavailable in the predicate SJM Confirm™ DM2102 device.
- **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.

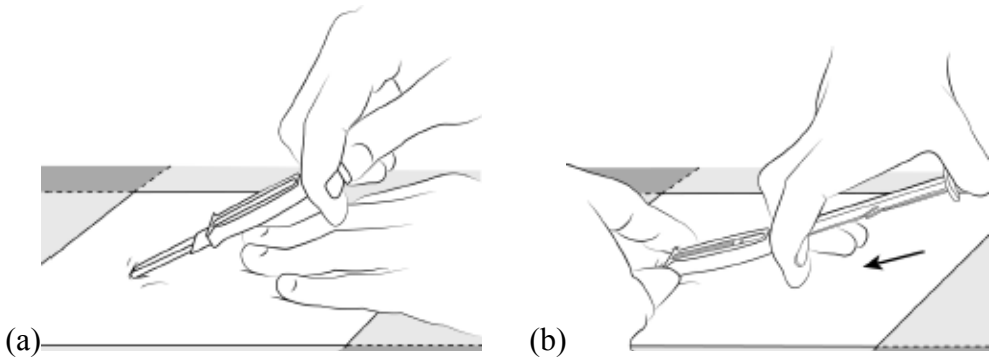

Figure 1: Insertion Process

- **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™.

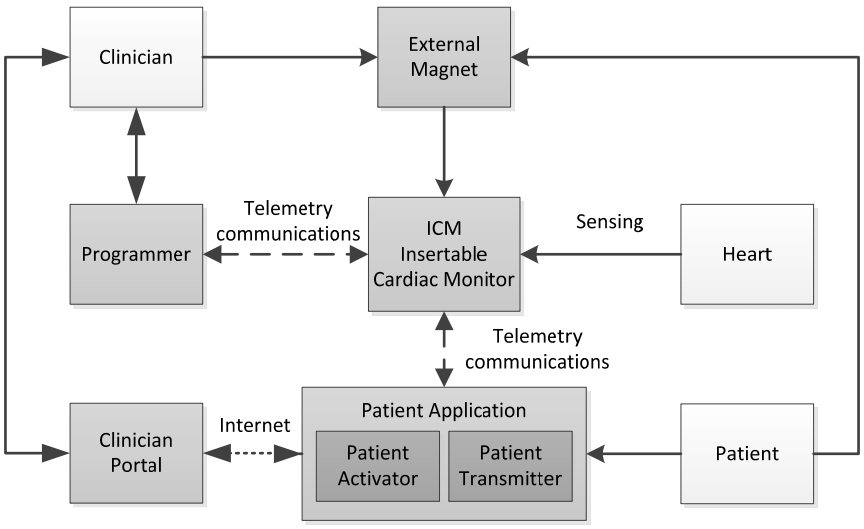

Figure 2: Block Diagram of Confirm Rx™ ICM System

The Confirm Rx™ ICM, DM3500, and the myMerlin™ mobile application, APP1000, are the subject of this premarket notification. The Merlin PCS programmer is already FDA approved. The Model 3330 v23.0.1 software for the Model 3650 Merlin PCS programmer and the Merlin.net MN5000 v7.5 software will be submitted under separate RTR PMA/S submissions. The magnet, Model 3111, is Class I exempt MDDS.

TECHNOLOGICAL CHARACTERISTICS

The Confirm Rx™ ICM (DM3500) is a smaller version of the predicate SJM Confirm™ ICM (DM2102) device (5.63 x 1.85 x 0.80 cm vs 4.95 x 0.95 x 0.33 cm in dimension) and uses Bluetooth® wireless telemetry instead of inductive telemetry to communicate with external devices, including the Merlin PCS programmer and the myMerlin™ mobile application. In correlation with the reduced size of the Confirm Rx™ ICM, the electrode spacing and surface area is decreased as compared to the SJM Confirm™ ICM (DM2102) (refer to Section 12 for details).

The patient activator and remote monitoring equipment for the predicate SJM Confirm™ ICM (DM2102) device is St. Jude Medical-provided custom hardware (patient activator) using analog telephone connectivity, whereas the remote monitoring equipment for the Confirm Rx™ ICM is the myMerlin™ mobile application, installed on a patient's or St. Jude Medical-provided mobile device, using built-in cellular and Wi-Fi connectivity.

Both the predicate SJM Confirm™ ICM (DM2102) and the Confirm Rx™ ICM are MR Conditional.

The Confirm Rx™ ICM firmware including device parameters, features, and detection algorithm are based on the predicate SJM Confirm™ ICM (DM2102) firmware.

Like the predicate SJM Confirm™ ICM (DM2102) device, 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), as is the predicate Medtronic Reveal LINQ™ (LNQ11), whereas the header material of the predicate SJM

Confirm™ ICM (DM2102) device is epoxy. The battery chemistry of the predicate SJM Confirm™ ICM (DM2102) device is lithium thionyl chloride, while the battery chemistry of the Confirm Rx™ device is lithium carbon monofluoride, as is the battery chemistry of the predicate Medtronic Reveal LINQ™ (LNQ11) device.

The implant tools, an incision and an insertion tool, are similar to the predicate Medtronic Reveal LINQ™ (LNQ11) system. The incision tool is comprised of polycarbonate and ABS material with a white colorant and has a stainless steel blade. The insertion tool consists of a housing and plunger component comprised of the same polycarbonate and ABS material with white colorant as the incision tool. Both the incision tool and insertion tool are external communicating devices with limited (< 24 hour) contact with tissue or bone.

Performance data is provided to support the determination of substantial equivalence.

SUBSTANTIAL EQUIVALENCE

The Confirm Rx™ ICM is substantially equivalent to the SJM Confirm™ (DM2102) ICM (K133481), and the Medtronic Reveal LINQ™ (LNQ11) ICM (K132649). The subject and the predicate devices are cardiovascular monitoring devices used to record and play back physiological signals. The indications for use for the Confirm Rx™ ICM are substantially equivalent to the indications for use for the predicate devices. Any differences in the technological characteristics between the devices do not raise any new issues of safety or effectiveness. Thus, the Confirm Rx™ ICM system is substantially equivalent to the predicate devices.

TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

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

- Software/Firmware Verification and System Validation
- Cybersecurity
- Bluetooth / coexistence
- Performance Testing (Animal GLP Study)
- Biocompatibility
- Sterilization
- Shelf Life
- Packaging
- Electromagnetic compatibility (EMC)
- Electrical safety
- MRI compliance
- Mechanical performance
- Usability testing

The Confirm Rx™ ICM leverages the existing market cleared SJM Confirm™ (DM2102) algorithms and functionality for which the clinical testing, performed on the SJM Confirm™ (DM2102) device per St. Jude Medical IDE G080090, is applicable and was not repeated.

510(k) SUMMARY

R-wave detection and device migration were verified via bench and animal testing for the Confirm Rx™ ICM DM3500.

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

CONCLUSION

The Confirm Rx™ ICM is an implantable cardiovascular monitoring device and shares its design and mechanism of action with the identified predicate devices. The results of testing demonstrate that the Confirm Rx™ ICM functions to its specifications, performs as intended, and exhibits the appropriate characteristics of an implantable cardiovascular monitoring device. The Confirm Rx™ ICM is substantially equivalent to the predicate devices in terms of technological characteristics, intended use, and performance.

SUMMARY

The Confirm Rx™ ICM System is substantially equivalent to the predicate devices.