November 2, 2017

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

Re: K173232
Trade/Device Name: myMerlin™ Mobile Application, Model APP1001
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: Class II
Product Code: MXC, DSI
Dated: October 3, 2017
Received: October 4, 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 (DICE) 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 (DICE) 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)*
K173232

Device Name

myMerlin™ Mobile Application, Model APP1001

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.

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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."

K173232

510(k) SUMMARY

Date Prepared:	October 3, 2017	
Submitter: Address: Phone:	St. Jude Medical, Cardiac Rhythm Management Division 15900 Valley View Ct. Sylmar, CA 91342 USA (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:	myMerlin™ Mobile Application, Model APP1001	
Model Number:	APP1001	
Classification Name:	Medical magnetic tape recorder (21 CFR 870.2800)	
Product Code:	MXC, DSI	
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) K163407: myMerlin™ Mobile Application Model APP1000

INDICATIONS FOR USE

The Indications for Use for the Confirm Rx™ 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.

K173232

510(k) SUMMARY

PRODUCT DESCRIPTION

The device description of the myMerlin™ mobile application Model APP1001 is as follows:

The myMerlin™ mobile application Model APP1001 is an application for patients who are implanted with the Confirm Rx™ Insertable Cardiac Monitor (ICM) Model DM3500 (K163407). The mobile application is used by patients to initiate recording of the heart's electrical activity by the Confirm Rx™ ICM device, read the information about the heart's activity from the Confirm Rx™ ICM device, and send this information to a clinician for remote monitoring. The myMerlin™ mobile application Model APP1001 is to be installed on a patient's mobile device with the iOS operating system which meets the specified minimum criteria for compatibility with the myMerlin™ mobile application.

The myMerlin™ mobile application Model APP1001 is the subject of this premarket notification. The Confirm Rx™ ICM Model DM3500 and the myMerlin™ mobile application Model APP1000 (Android) were cleared on September 29, 2017 per 510(k) K163407.

Remote monitoring is performed via the Merlin.net Model MN5000 clinician portal software, for which an approvable letter pending 510(k) K163407 clearance was received on May 2, 2017 for PMA Supplement P910023/S381 (bundled). No additional changes to Merlin.net Model MN5000 are required due to the inclusion of the myMerlin mobile application Model APP1001.

TECHNOLOGICAL CHARACTERISTICS

The fundamental technological characteristics of the myMerlin™ mobile application Model APP1001 are the same as the predicate myMerlin™ mobile application Model APP1000 (K163407). Model APP1001 runs on the iOS operating system, while Model APP1000 (K163407) runs on the Android operating system. The myMerlin™ mobile application, both candidate Model APP1001 and predicate Model APP1000 (K163407), is software that is installed on a patient's mobile device, which uses built-in Bluetooth telemetry for communication with the Confirm Rx™ ICM DM3500 (K163407) and built-in cellular and Wi-Fi connectivity for transmission of data to the Merlin.net Model MN5000 clinician portal (reference PMA P910023/S381, bundled) for remote monitoring.

NON-CLINICAL TEST SUMMARY

The risk analysis method used to assess the impact of the modification of the myMerlin™ mobile application Model APP1001 documents the investigation of hazards and mitigation of risks associated with its use 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 candidate device meets its predetermined design and performance specifications and that the product is substantially equivalent to the predicate device (Model APP1000, K163407).

510(k) SUMMARY

CONCLUSION (SUBSTANTIAL EQUIVALENCE)

The results of the verification and validation tests and the risk analysis have demonstrated the myMerlin™ mobile application Model APP1001 functions in accordance with product specifications. The myMerlin™ mobile application (candidate Model APP1001; predicate Model APP1000, K163407) is used in conjunction with the Confirm Rx™ Insertable Cardiac Monitor (ICM) System, Model DM3500 (K163407); therefore, the same indications that are listed in the Confirm Rx™ ICM instructions for use apply. The indications for use are not impacted by the inclusion of the myMerlin™ mobile application Model APP1001. The fundamental scientific technology of the predicate myMerlin™ mobile application (APP1000, K163704) is the same as for the candidate myMerlin mobile application Model APP1001. Thus, the myMerlin™ mobile application Model APP1001 to be substantially equivalent to the predicate myMerlin™ mobile application (APP1000, K163407, cleared on September 29, 2017)