DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

Division of Cardiovascular Devices
Pacing, Defibrillator & Leads Branch

SUMMARY OF:

P010031/S296
Concerto II CRT-D Model D274TRK; Consulta CRT-D Models D204TRM, D224TRK; and Maximo II CRT-D Models D264TRM, D284TRK

P890003/S247
DDMA Software Model 2491

P010015/S157
Consulta CRT-P ModelC4TR01; and Syncra CRT-P Model C2TR01

P980016/S343
Maximo II ICD Models D264DRM, D284DRG, D284VRC; Secura ICD Models D204DRM, D224DRG, D224VRC; and Virtuoso II DR/VR ICD Models D274DRG, D274VRC

P980035/S264
Advisa DR IPG Model A4DR01

Application software Model 9995 Version 7.4 for CareLink Programmer Model 2090

Medtronic, Inc.
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BACKGROUND/REASON FOR SUPPLEMENT

The 180-day PMA/S (subject file) was submitted by Medtronic (the company) for requesting the approval of the Application software Model 9995 Version 7.4 for the CareLink Model 2090, be used with the above referenced implantable devices. The modifications for the software are:

1. Pacing rate limit for Consulta CRT-P and CRT-D, Syncra CRT-P, Concerto II CRT-D,and Maximo II CRT-D.

2. Modify the longevity estimator for Consulta CRT-P, Syncra CRT-P, and Advisa DR.

3. RAMware update for the European Investigational Device, Advisa DR.

4. Correct User interfact for the Ventricular Sensor Response (VSR) of the Syncra CRT-P.

5. Spanish translation of LVpace Polarity for Consulta CRT-P, Syncra CRT-P.

INDICATIONS FOR USE

NOTE: The company claims, "the indications for use" are unaffected by the purposed changes in this PMA/S.

DEVICE DESCRIPTIONS

The subject PMA/S contains the software modifications for the programmer, and the following is the software changes for the Model 9995 v7.4 (Gen2 Software application):

Change to the Pacing Rate Limit in Gen2 CRT devices.

Update the "look-up" table used by the Remaining Longevity Estimator feature.

Display the Arrhythmia Intervention field (i.e. Ventricular Sense Response) on the user interface.

Correct the Spanish translation "LV Ring to Can" (OUS only)

Modified battery thresholds (ERI/EOS) for seventy nine (79) European Investigational Advisa DR devices. The update does not affect the FDA approved Advisa DR IPG as it uses a different battery.

DDMA Model 2491 (CareLink Device Data Management Application):

Update the "look-up" table used by the Remaining Longevity Estimator feature are implemented in the XMLTU component of the DDMA.

THE SUMMARY FOR THE REVIEW

The company claims, there are no changes to the implanted device firmware for U.S. models and market released devices.

The software testing verified that Model 9995 v7.4 application software operates per specification. The Systems verification and validation testing was conducted with Model 9995 v7.4 software to ensure that the software performs as intended during simulated clinical situations. The company claims, through the systems testing, Models 9995 v7.4 software is qualified and is acceptable for human use.

The company performed the software hazard analysis for software version 7.4, and this report is part of this submittal. Based on the report, it is acceptable.

The company provided the requirements and the specifications for the software modifications in the subject file. Based on the information in those documents, it is acceptable.

The following software information was provided by the company. Those are:

Architecture Design Chart
Traceability Analysis
Model 9995 and XMLTU Version Description Documents
Verification Documentation / Software Development Environment Description

The following system information was provided by the company. Those are:

System Verification and Validation Testing
System Validation Test Plan

System Validation Test Results
System Verification Test Plan, Test Procedure, and Test Report

Based on the information in this PMA/S, the company has tested the software modifications and tested the programmer Model 2090 with the application software version 7.4. Based on the test reports in this PMA/S, all the test cases are passed, and the company claims, no anomaly was observed during the record run for all the test cases.

BIOCOMPATIBILITY: N/A

ANIMAL STUDY: N/A

CLINICAL DATA: N/A

LABELING:

The software version number will be updated.

CONCLUSION

Based on the information in the file, the company has provided the appropriate data to demonstrate the subject device is safe and effective.