



MEMORANDUM

SUMMARY OF:

P890003/S251
P980016/S362
Software Model 9995 v7.4 Addition of New Models
Medtronic

BACKGROUND

This PMA supplement requests approval for the use of recently approved software 9995 version 7.4 (P980016/S343) and associated DDMA software 2491 (P890003/S247) with recently approved device models D264VRM and D204VRM (P980016/S280, approved May 2, 2012). These device models were under review at the time the software revision was submitted to FDA and therefore could not be included in the original submission. The device models were approved with software 9995 version 7.3.

The application software 9995 is used for all products in the Medtronic Gen2 ICD platform. The change from version 7.3 to 7.4 included changes that do not impact the device models D264VRM and D204VRM, but these models will utilize the updated software. The testing performed on software 9995 version 7.4 covers these two new device models. No further testing is required. This PMA supplement is for approval to use software 9995 version 7.4 with device models D264VRM and D204VRM.

INDICATIONS FOR USE

The indications for use are not affected by the changes.

DEVICE DESCRIPTION AND CHANGE DESCRIPTION

The changes covered under this submission are implemented in the following software components:

Model 9995 v7.4 (Gen2 Software application)

- 1) Change to the Pacing Rate Limit in Gen2 CRT devices.
- 2) Update the “look-up” table used by the Remaining Longevity Estimator feature.
- 3) Display the Arrhythmia Intervention field (i.e. Ventricular Sense Response) on the user interface.
- 4) Correct the Spanish translation “LV Ring to Can” (OUS only)
- 5) Modified battery thresholds (ERI/EOS) for (b) (4) 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)

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

These changes are identical to the changes included in the original submission for software 9995 version 7.4 and DDMA Model 2491. In this submission, the sponsor is requesting approval to use these latest versions of software with recently approved device models D264VRM and D204VRM.

RISK ANALYSIS

A complete risk management summary report for software Model 9995 updates was included in Gen2 (v7.4) (b) (4) (b) (4) which was included in the original submission (P980016/S343). The complete risk management summary concluded that the software updates are safe and acceptable for patient implantable use from a safety risk perspective. All identified system hazard scenarios have been either mitigated or are at an acceptable level of residual risk.

Since there is no new information, this information was found acceptable.

SOFTWARE

Software Model 9995 v7.4 and associated DDMA software 2491 has already been reviewed and approved under P890003/S247. In this submission, the sponsor is adding support for two additional models that were not included in the original submission since they were under review at that time.

To confirm that the new models were adequately tested an interactive discussion was held. The sponsor was asked to confirm that application software v7.4 was tested with the new models (D264VRM, D204VRM), and which verification and validation tests apply and their results. The sponsor responded that none of the changes to the software directly impacted the functionality included in D204VRM and D264VRM. The sponsor also identified which tests were completed with these new models. The response was reviewed and found acceptable.

OTHER REVIEW ELEMENTS

The following areas are not relevant for the subject review:

- Clinical
- Animal Testing
- EMC/EMI
- Biocompatibility
- Manufacturing
- Human Factors
- Packaging, sterilization, shelf-life
- Labeling
- Marketing
- Post Market

