SUMMARY OF:

P980016/S361
Protecta ICD Models D334DRG, D334VRG; Protecta DF4 ICD Models D334DRM, D334VRM; Protecta XT ICD Models D314DRG, D314VRG; Protecta XT DF4 ICD Models D314DRM, D314VRM.

P010031/S314
Protecta CRT-D Model D334TRG; Protecta DF4 CRT-D Model D334TRM; Protecta XT CRT-D Model D314TRG; Protecta XT DF4 CRT-D Model D314TRM.

2090 Programmer SW009 v1.3 for the Protecta TWOS and LN discrimination Update

Medtronic, Inc.
8200 Coral Sea Street
Moundsview, MN 55112

BACKGROUND/REASON FOR SUPPLEMENT

The 180-day PMA/S (subject file) was submitted by Medtronic Inc. (the company) for requesting the approval of the Protecta TWOS and LN Discrimination Update SW009 v1.3 for the above referenced implantable devices.

The software modifications are:

1. Ventricular Pacing Rate Limit: (b) (4) (b) (4) (b) (4) .
2. Atrial Pacing Rate Limit: (b) (4) (b) (4)
3. Oversensing Discrimination: (b) (4) (b) (4) .

The software update will be downloaded to devices in the (b) (4) (b) (4) . (b) (4)

INDICATIONS FOR USE

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

DEVICE DESCRIPTIONS

The software modifications are:

1. Ventricular Pacing Rate Limit:

(b) (4) [redacted]

2. Atrial Pacing Rate Limit:

(b) (4) [redacted]

3. Oversensing Discrimination: (b) (4) [redacted]
(b) (4) [redacted]

   The company proposes to expand the scenarios in which (b) (4) [redacted] is applied by (b) (4) [redacted] is only applied when sensed event electrogram amplitudes are all less than 32mV.

(b) (4) [redacted]

(b) (4) [redacted]

THE SUMMARY FOR THE REVIEW

The company claims, there are no change to the hardware, and only the software modifications in the subject file. The reviewer agrees and it is acceptable.

The company claims, it has thoroughly evaluated updates through (b) (4) [redacted] to confirm that the requirements are met, and reliability is assured for its intended use. The firmware (b) (4) [redacted] assessments have been successfully completed for the changes. All components and (b) (4) [redacted] s performed according to test and device requirements, and met the predetermined acceptance criteria. The following non-clinical testing activities are included in this submission:

- Firmware Verification Testing
- Software Verification Testing
- System Verification and Validation Testing
- Simulated Use (Tape) Testing

Firmware:

The company claims, the firmware verification testing was executed at the end of the development process to demonstrate that the applicable testable firmware requirements have been correctly implemented. All requirements passed and no anomalous or unexpected operations occurred during the testing.

(b) (4) [redacted]

The software anomalies were acceptable, since those issues will not raise any safety issue, etc.

BIOCOMPATIBILITY: N/A

ANIMAL STUDY: N/A

CLINICAL DATA: N/A

LABELING:

The label for the software was provided in the file, it is acceptable.

CONCLUSION

Based on the information in the file and the conference calls, the company has provided the appropriate data for the approval of the subject device.