SUMMARY OF:

P980016/S548
EVERA S DR ICD DDBC3D1, DDBC3D4; EVERA S VR ICD DVBC3D1, DVBC3D4; EVERA XT DR ICD DDBB1D1, DDBB1D4; EVERA XT VR ICD DVBB1D1, DVBB1D4;

P010031/S511
BRAVA CRT-D DTBC1D4, DTBC1D1; BRAVA QUAD CRT-D DTBC1Q1, DTBC1QQ; VIVA QUAD S CRT-D DTBB1Q1, DTBB1QQ; VIVA QUAD XT CRT-D DTBA1Q1, DTBA1QQ; VIVA S CRT-D DTBB1D1, DTBB1D4; VIVA XT CRT-D DTBA1D1, DTBA1D4

BACKGROUND/REASON FOR SUPPLEMENT

The subject 180 Day PMA/S was received on September 4, 2015, submitted by Medtronic Inc. (the company) is requesting for three new alternate ICs to be used in the above devices. The subject file contains new design and new manufacture process for the three ICs. Those three ICs will be refer as IC(A), IC(B), and IC(C).

INDICATIONS FOR USE

NOTE: The company claims, "the indications for use" are unaffected by the purposed changes in this PMA/S. The following is the Indications For Use Statements.

Brava CRT-D (DTBC1D1, DTBC1D4); Brava Quad CRT-D (DTBC1Q1, DTBC1QQ0:

The Brava / Brava Quad CRT-D system is indicated for ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias and for providing cardiac resynchronization therapy in heart failure patients on stable, optimal heart failure medical therapy if indicated, and meet any of the following classifications:

- New York Heart Association (NYHA) Functional Class III or IV and who have a left ventricular ejection fraction ≤35% and a prolonged QRS duration

- Left bundle branch block (LBBB) with a QRS duration ≥130 ms, left ventricular ejection fraction ≤30%, and NYHA Functional Class II

- NYHA Functional Class I, II, or III and who have left ventricular ejection fraction ≤50% and atrioventricular block (AV block) that are expected to require a high percentage of ventricular pacing that cannot be managed with algorithms to minimize right ventricular pacing. Optimization of heart failure medical therapy that is limited due to AV block or the urgent need for pacing should be done post implant

Viva Quad S CRT-D (DTBB1Q1, DTBB1QQ: Viva Quad XT CRT-D (DTBA1Q1, DTBA1QQ); Viva S CRT-D (DTBB1D1, DTBB1D4); Viva XT CRT-D (DTBA1D1, DTBA1D4):

The Viva Quad / Viva CRT-D system is indicated for patients who require ventricular

antitachycardia pacing and ventricular defibrillation for automated treatment of lifethreatening ventricular arrhythmias, for use in patients with atrial tachyarrhythmias, or those patients who are at significant risk for developing atrial tachyarrhythmias and for providing cardiac resynchronization therapy in heart failure patients on stable, optimal heart failure medical therapy if indicated, and meet any of the following classifications:

- New York Heart Association (NYHA) Functional Class III or IV and who have a left ventricular ejection fraction ≤35% and a prolonged QRS duration

- Left bundle branch block (LBBB) with a QRS duration ≥130 ms, left ventricular ejection fraction ≤30%, and NYHA Functional Class II

- NYHA Functional Class I, II, or III and who have left ventricular ejection fraction ≤50% and atrioventricular block (AV block) that are expected to require a high percentage of ventricular pacing that cannot be managed with algorithms to minimize right ventricular pacing. Optimization of heart failure medical therapy that is limited due to AV block or the urgent need for pacing should be done post implant.

Evera S DR ICD (DDBC3D1, DDBC3D4):

The Evera S DR system is indicated to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of lifethreatening ventricular arrhythmias. In addition, the device is indicated for use in the above patients with atrial tachyarrhythmias, or those patients who are at significant risk of developing atrial tachyarrhythmias. Notes:

- The use of the device has not been demonstrated to decrease the morbidity related to atrial tachyarrhythmias.

- The effectiveness of high-frequency burst pacing (atrial 50 Hz Burst therapy) in terminating device-classified atrial tachycardia (AT) was found to be 17% and in terminating device-classified atrial fibrillation (AF) was found to be 16.8% in the VT/AT patient population studied.

- The effectiveness of high-frequency burst pacing (atrial 50 Hz Burst therapy) in terminating device-classified atrial tachycardia (AT) was found to be 11.7% and in terminating device-classified atrial fibrillation (AF) was found to be 18.2% in the
AF-only patient population studied.

Evera S VR ICD (DVBC3D1, DVBC3D4):

The Evera S VR system is indicated to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of lifethreatening ventricular arrhythmias.

Evera XT DR ICD (DDBB1D1, DDBB1D4):

The Evera XT DR system is indicated to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of lifethreatening ventricular arrhythmias. In addition, the device is indicated for use in the above patients with atrial tachyarrhythmias, or those patients who are at significant risk of developing atrial tachyarrhythmias. Notes:

- The use of the device has not been demonstrated to decrease the morbidity related to atrial tachyarrhythmias.

- The effectiveness of high-frequency burst pacing (atrial 50 Hz Burst therapy) in terminating device-classified atrial tachycardia (AT) was found to be 17% and in terminating device-classified atrial fibrillation (AF) was found to be 16.8% in the VT/AT patient population studied.

- The effectiveness of high-frequency burst pacing (atrial 50 Hz Burst therapy) in terminating device-classified atrial tachycardia (AT) was found to be 11.7% and in terminating device-classified atrial fibrillation (AF) was found to be 18.2% in the
AF-only patient population studied.

Evera XT VR ICD (DVBB1D1, DVBB1D4):

The Evera XT VR system is indicated to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of lifethreatening ventricular arrhythmias.

DEVICE DESCRIPTIONS

The subject file contains three newly designed ICs with the new manufacture process, those are: IC(A), IC(B), and IC(C). Those three ICs will be part of the hybrid within the implantable devices.

IC(A) is used in the high-energy therapy circuit of the ICD. It is a high voltage\high current switch that switches the current path and direction between the leads based on the therapy configuration setting.

IC(B) is used to turn on the components that are in the high voltage delivery circuit which are used to determine the high voltage delivery pathway based on the therapy configuration setting.

IC(C) is a blocking MOSFET (Metal Oxide Semiconductor Field Effect Transistor) which provides circuitry protection from damage due to external defibrillation or electrosurgical cautery.

DEVICE TESTING/REVIEW

Non-clinical bench testing was performed to verify the ICs; Reliability demonstration and process capability have been included as part of the component qualifications at the IC level for the manufacture process; and the verification testing has been performed at the hybrid, electronic module assembly level, and the final device level.

In additionally, the updated hybrid test software has successful completed verification and validation testing. All testing has passed the current hybrid and finished device design requirements, demonstrating acceptable performance by the alternate ICs. There are no changes to the final device form, fit or function.

BIOCOMPATIBILITY: N/A

ANIMAL STUDY: N/A

CLINICAL DATA: N/A

LABELING: : N/A

CONCLUSION

.Based on the information in the subject file with the past FDA approval actions, I recommend the approval for the subject PMA/S file.