DATE: 29 January 2010

FROM: (b)(6)

SUBJECT: P030054/S131, P910023/S215

CONTACT: (b)(6)

TO: THE RECORD

BACKGROUND/ REASON FOR SUPPLEMENT

SJM requested approval for the Current Accel ICD models CD2215/CD1215 and Promote Accel CRT-D model CD3215 Pulse Generators and the Model 3330 Version 7.1.2.1.

REVIEW TEAM

(b)(6) Software Reviewer and Lead Reviewer, CDRH/ODE/DCD/PDLB
(b)(6), Initial Lead Reviewer, CDRH/ODE/DCD/PDLB
(b)(6) MD, Clinician, CDRH/ODE/DCD/PDLB
(b)(6) PhD, Statistician, CDRH/OSB

INDICATIONS FOR USE

The system is intended to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias. AF suppression pacing is indicated for suppression of paroxysmal or persistent atrial fibrillation in patients with the above ICD indication and sinus node dysfunction. In patients indicated for an ICD, the system is also intended:

• to provide a reduction of the symptoms of moderate to severe heart failure (NYHA Functional Class III or IV) in those patients who remain symptomatic despite stable, optimal medical therapy (as defined in the clinical trials section) and have a left ventricular ejection fraction less than or equal to 35% and a prolonged QRS duration

• to maintain synchrony of the left and right ventricles in patients who have undergone an AV nodal ablation for chronic (permanent) atrial fibrillation and have NYHA Class II or III heart failure.

DEVICE DESCRIPTION

The Current Accel ICD models 2215-30, 2215-36, 1215-30, and 1215-36 and Promote Accel CRT-D models 3215-30 and 3215-36 pulse generators are similar in function to legally marketed Current + ICD and Promote + CRT-D pulse generators, except the Current Accel and Promote Accel devices have the ACap Confirm, Ventricular Autocapture and BiVCap confirm features. The devices are available in both standard energy, 30 joules and high energy 36 joules versions. The devices are supported by the legally marketed Model 3650 Merlin PCS with the Model 3330 Version 7.1 software (or higher).

No changes to shelf life, biomaterials, sterilization, manufacturing, etc. as compared to the predicate Current + ICD and Promote + CRT-D pulse generators are proposed.

PRECLINICAL/BENCH

The Current Accel and Promote Accel devices are identical to the legally marketed Current + and Promote + devices, with the exception of minor updates to the device software (firmware).

BIOCOMPATIBILITY/MATERIALS : Not applicable

ANIMAL STUDIES: Not applicable

ELECTRICAL SAFETY: Not applicable

MECHANICAL SAFETY: Not applicable

SOFTWARE: The software reviewer recommends approval of the subject. (Refer to Attachment 1.) The software reviewer indicates: "The proposed devices include software development for the following features studied within G080060: ACap Confirm, Ventricular AutoCapture (RVAC), LVCap Confirm and RVCap Confirm (BiVCap Confirm). The subject SW serves to incorporate the changes within an existing platform—with no change to hardware." Of further note: "The documentation provided sufficiently details adequate software development in alignment with previous practices. Further, the features proposed within the subject were rigorously studied within a related IDE (G080060): No significant SW anomaly is associated with the study."

CLINICAL DATA

The Current /Promote Automaticity IDE study was conducted to show that the St. Jude Medical Current Accel ICD model 2215/1215 and Promote Accel CRT-D model 3215 are safe and effective. This study was a prospective, non-randomized, multi-center clinical trial. Patients were enrolled at 15 investigational centers located in the U.S. A total of 128 patients were enrolled. Data are presented on the first 19, 38, and 45 patients available to complete the primary endpoint analysis for the ACap Confirm, VAC, and LVCap/RVCap Confirm features, respectively, as defined in the protocol. The total time of follow-up was 747.6 patient months. The average time of follow-up was 5.84 ± 1.96 (range 1.38 to 9.00) patient months.

At scheduled visits, the patients were seen at the clinic or physician's office for the following evaluations: Device interrogation; Sensing amplitudes – P and R-wave measurements; Lead impedance measurements; Manual (decrement) capture threshold tests; Automatic (Cap Confirm) capture threshold test, with Setup tests where applicable

Following internal discussion, the clinician and statistician recommended full approval without deficiencies. Refer to Attachments 2 and 3.

SUMMARY OF INTERACTIVE REVIEW/CORRESPONDENCE

23 January 2010: Received clarification from SJM regarding statistical concerns

15 January 2010: SJM, FDA discussion regarding software development life-cycle processes

CONCLUSION

All items were clarified during interactive review. No further concerns are noted.

RECOMMENDATION - I recommend that the supplement be Approved.

(b)(6) Date

(b)(6) Date