DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

NOV 2 9 2011

Ms. Elisabeth Neely
Senior Director, Regulatory Affairs
St. Jude Medical
Cardiac Rhythm Management Division
701 E. Evelyn Avenue
Sunnyvale, CA 94086

Re: P030054 / S173
Promote Q Model CD3221-36 CRT-D
Promote Quadra Models CD 3245-40/40Q CRT-D
Unify Quadra CRT-D Models CD3249-40/40Q CRT-D
Quartet Model 1458Q LV Lead
Model 3330 version 12.1.1 Programmer Software
Filed: October 29, 2010
Amended: March 14, 2011; April 5, 2011; May 2, 2011; June 3, 2011; August 15, 2011; October 11, 2011
Procode: NIK

Dear Ms. Neely:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its evaluation of your premarket approval application (PMA) supplement, which requested approval for Promote Q Model CD3221-36 CRT-D, Promote Quadra Models CD 3245-40/40Q CRT-D, Unify Quadra CRT-D Models CD3249-40/40Q CRT-D, Quartet Model 1458Q LV Lead, and Model 3330 version 12.1.1 Programmer Software. Based upon the information submitted, the PMA supplement is approved. You may begin commercial distribution of the device as modified by your PMA supplement in accordance with the conditions described below.

The sale and distribution of this device are restricted to prescription use in accordance with 21 CFR 801.109 and under section 515(d)(1)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (the act). FDA has determined that this restriction on sale and distribution is necessary to provide reasonable assurance of the safety and effectiveness of the device. Your device is therefore a restricted device subject to the requirements in sections 502(q) and (r) of the act, in addition to the many other FDA requirements governing the manufacture, distribution, and marketing of devices.

Continued approval of this PMA is contingent upon the submission of periodic reports, required under 21 CFR 814.84, at intervals of one year (unless otherwise specified) from the date of approval of the original PMA. Two copies of this report, identified as "Annual Report" (please use this title even if the specified interval is more frequent than one year) and bearing the applicable PMA reference number, should be submitted to the address below. The Annual Report should indicate the beginning and ending date of the period covered by the report and should include the information required by 21 CFR 814.84.

In addition to the above, and in order to provide continued reasonable assurance of the safety and effectiveness of the device, the Annual Report must include, separately for each model number (if applicable), the number of devices sold and distributed during the reporting period, including those distributed to distributors. The distribution data will serve as a denominator and provide necessary context for FDA to ascertain the frequency and prevalence of adverse events, as FDA evaluates the continued safety and effectiveness of the device.

In addition, because your device is a pacemaker, implantable cardioverter-defibrillator (ICD), or system lead, FDA has determined that the following additional information is necessary to provide continued reasonable assurance of the safety and effectiveness of the device. In the Annual Report, provide the following information known by or reported to the applicant:

1. The number of pulse generators / leads domestically implanted and the number of reported explants and deaths.

2. A breakdown of the reported deaths into pulse generators / leads related and non-pulse generator / lead related.

3. A breakdown of the reported explants into the number reported that were:

    a. For pacemakers and pulse generators: at end of battery life, the number that had complications not resolvable by programming, and, as applicable, the numbers that experienced other safety and effectiveness complications as ascertained by the user, applicant, or otherwise, or

    b. For leads: associated with mechanical failure, associated with clinical complications, and as applicable, the numbers that experienced other safety and effectiveness complications as ascertained by the user, applicant, or otherwise.

4. The number of pulse generators / leads returned to the applicant for cause from domestic sources, with a breakdown into:

    a. For pacemakers and pulse generators: the number currently in analysis, the number operating properly, and the number at normal battery depletion and failed (with the failure mechanisms described).

    b. For leads: the number currently in analysis, the number operating properly, the number failed (with failure mechanisms described); broken down into groupings for full leads and partial leads.

5. A cumulative survival table for the pulse generators / leads.

In addition to the Annual Report requirements, you must provide the following data in post-approval study reports (PAS). Two copies, identified as "PMA Post-Approval Study Report" and bearing the applicable PMA reference number, should be submitted to the address below.

Quadripolar Pacing PAS: This is a nonrandomized, multi-site, study of 1,884 new patients enrolled into the study to achieve an evaluable sample size of 1,036. It is expected that 40-60% of IDE patients will roll over into the PAS, therefore the total sample size would be 1955-1990. The study will be conducted per the final protocol submitted May 2, 2011, version 60030283/C – Clinical (P030054/S173/A003). The primary objectives of this study are to assess the safety and efficacy of the Quadripolar CRT-D device system at 5 years in a patient population indicated for cardiac resynchronization therapy.

There are three primary endpoints and one secondary endpoint in this study. The first primary endpoint hypothesis is to demonstrate that the Quartet Model 1458Q LV lead-related complication-free rate is greater than 92.5% at five years post-implant; the second primary endpoint hypothesis is to demonstrate that the system-related complication-free rate is greater than 80% at five years. The complication free rate will be estimated based on clinical adverse events including: abnormal LV lead performance (pacing impedance, elevated pacing thresholds, and loss of capture), lead insulation damage, diaphragmatic/phrenic nerve stimulation, cardiac perforation, lead dislodgement. The third primary endpoint hypothesis is to find the mean programmed LV lead pacing threshold at 5 years to be less than 3.0 V.

The secondary objective is to characterize the complication rate of the Quartet™ Model 1458 LV lead, and to perform a trend analysis of all complications. Subjects will be followed through five years post-implant. Newly enrolled patients who have a successful system implant will be seen at 6 months (+ 45 days) after implant and every 6 months (+ 60 days) thereafter until the patient reaches the 5 year visit. Rollover patients from the IDE study will be followed every 6 months (+ 30 days) until study completion.

FDA would like to remind you that you are required to submit PAS Progress Reports every six months. The PAS Progress Reports should be submitted separately from the Annual Reports. Please refer to the guidance document on how to handle post-approval studies imposed by approval orders, located at the following website:
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070974.htm

Be advised that the failure to conduct any such study in compliance with the good clinical laboratory practices in 21 CFR part 58 (if a non-clinical study subject to part 58) or the institutional review board regulations in 21 CFR part 56 and the informed consent regulations in 21 CFR part 50 (if a clinical study involving human subjects) may be grounds for FDA withdrawal of approval of the PMA.

Before making any change affecting the safety or effectiveness of the device, you must submit a PMA supplement or an alternate submission (30-day notice) in accordance with 21 CFR 814.39.

All PMA supplements and alternate submissions (30-day notice) must comply with the applicable requirements in 21 CFR 814.39. For more information, please refer to the FDA guidance document entitled, "Modifications to Devices Subject to Premarket Approval (PMA) - The PMA Supplement Decision-Making Process" (www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089274.htm).

You are reminded that many FDA requirements govern the manufacture, distribution, and marketing of devices. For example, in accordance with the Medical Device Reporting (MDR) regulation, 21 CFR 803.50 and 21 CFR 803.52, you are required to report adverse events for this device. Manufacturers of medical devices, including in vitro diagnostic devices, are required to report to FDA no later than 30 calendar days after the day they receive or otherwise becomes aware of information, from any source, that reasonably suggests that one of their marketed devices:

1. May have caused or contributed to a death or serious injury; or

2. Has malfunctioned and such device or similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Additional information on MDR, including how, when, and where to report, is available at www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

In accordance with the recall requirements specified in 21 CFR 806.10, you are required to submit a written report to FDA of any correction or removal of this device initiated by you to: (1) reduce a risk to health posed by the device; or (2) remedy a violation of the act caused by the device which may present a risk to health, with certain exceptions specified in 21 CFR 806.10(a)(2). Additional information on recalls is available at www.fda.gov/Safety/Recalls/IndustryGuidance/default.htm.

CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

Failure to comply with any post-approval requirement constitutes a ground for withdrawal of approval of a PMA. The introduction or delivery for introduction into interstate commerce of a device that is not in compliance with its conditions of approval is a violation of law.

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with copies of all approved labeling in final printed form. Final printed labeling that is identical to the labeling approved in draft form will not routinely be reviewed by FDA staff when accompanied by a cover letter stating that the final printed labeling is identical to the labeling approved in draft form. If the final printed labeling is not identical, any changes from the final draft labeling should be highlighted and explained in the amendment.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing. One of those three copies may be an electronic copy (eCopy), in an electronic format that FDA can process, review and archive (general information: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.htm; clinical and statistical data: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm136377.htm).

U.S. Food and Drug Administration
Center for Devices and Radiological Health
PMA Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

If you have questions concerning this approval order, please contact (b) (6) at (b) (6)

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health