DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

June 6, 2013

Jennifer Wong
Regulatory Affairs Manager
St. Jude Medical
6901 Preston Road
Plano, TX 75024

Re: P910023/S309 Ellipse/Fortify Assura Families
P880086/S229 Affinity/Integrity/Victory/Zephyr/Accent Families
P030035/S107 Frontier/Frontier II/Anthem Families
P880006/S084 Sensolog/Dialog/Regency Families
P970013/S054 Microny Family
P030054/S238 Quadra Assura/Unify Assura Families
Filed: November 14, 2012
Amended: December 26, 2012, March 14, 2013
Procode: LWS, NIK, OSR

Dear Ms. Wong:

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 the following new Ellipse/Quadra Assura/Fortify Assura implantable cardioverter defibrillator (ICD) and cardiac resynchronization therapy defibrillator (CRT-D) models:

- Ellipse VR ICD (CD1411-36, CD1411-36Q, CD1411-36C, CD1411-36QC)
- Fortify Assura VR ICD (CD1357-40, CD1357-40Q, CD1357-40C, CD1357-40QC)
- Ellipse DR ICD (CD2411-36, CD2411-36Q, CD2411-36C, CD2411-36QC)
- Fortify Assura DR ICD (CD2357-40, CD2357-40Q, CD2357-40C, CD2357-40QC)
- Unify Assura CRT-D (CD3357-40, CD3357-40Q, CD3357-40C, CD3357-40QC)
- Quadra Assura CRT-D (CD3365-40, CD3365-40Q, CD3365-40C, CD3365-40QC)

as well as Model 3330 Version 17.1 Software for the Model 3650 Merlin Patient Care System Programmer, Model EX2000 Version 6.5 Software for the Models EX1150 and EX1100 Merlin@Home Transmitters, and Model MN5000 Version 6.5 Software for the Merlin.net System. 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). The device is further restricted under section 515(d)(1)(B)(ii) of the act insofar as the labeling must specify the specific training or experience practitioners need in order to use the device. FDA has determined that these restrictions on sale and distribution are 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 domestically implanted and the number of reported explants and deaths.

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

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.

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 Danielle Dorfman at (301)796-9350.

Sincerely yours,

Bram D. Zuckerman -S

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