Re: CareLink Encore™ 29901 Programmer2090 for P890003/S254
    Reveal

    P010031/S319
    Concerto II CRT-D, Consulta CRT-D, Maximo II CRT-D, Maximo II DF4, Insync III
    Protect, Insync II Protect, Concerto

    P980035/S280
    Kappa 600, Kappa 650, Kappa 700, Kappa 800, Kappa 900, Adapta, Sensia, Relia,
    Enpulse, Enrhythm, Advisa, Versa, Sigma

    P010015/S166
    Insync III, Consulta CRT-P, Syncra CRT-P

    P990001/S105
    Vitatron desktop software application, C60 DR, C20 SR, T60 DR

    P980016/S366
    Virtuoso II, Maximo II, Secura DF4, Secura, Entrust, Virtuoso
    Filed: July 17, 2012
    Amended: November 8, and 27, 2012, and January 17, 2013
    Procide: NIK, LWS, NVZ, and NKE

Dear Mr. Mohiuddin:

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 above referenced devices. 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
(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 James Lee at (301) 796-6360.

Sincerely yours,

Owen P. Faris -S

for

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