



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Ms. Claudia Manikam
ELA Medical Inc.
2905 Northwest Boulevard, Suite 40
Plymouth, MN 55441

APR - 7 2010

Re: P980049/S050
Paradym VR Model 8250 and DR Model 8550 with Smartview 2.18UG1 Programmer Software

P060027/S015
Paradym CRT-D Model 8750 with Hardware and Manufacturing Changes and Labeling and Programmer Software Changes to the Ovatio VR Model 6250, DR Model 6550 and CRT-D Model 6750

Filed: September 24, 2009
Amended: January 25, 2010

Dear Ms. Manikam:

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 Paradym VR Model 8250 and DR Model 8550 with Smartview 2.18UG1 Programmer Software and the Paradym CRT-D Model 8750 with Hardware and Manufacturing Changes and Labeling and Programmer Software Changes to the Ovatio VR Model 6250, DR Model 6550 and CRT-D Model 6750. The device, as modified, will be marketed under the trade name Paradym VR Model 8250 and Paradym DR Model 8550 with Smartview 2.18UG1 and is indicated for use in patients who are at high risk of sudden cardiac death due to ventricular tachyarrhythmias and who have experienced one of the following situations: Survival of at least one episode of cardiac arrest manifested by the loss of consciousness) due to ventricular tachyarrhythmia, recurrent poorly tolerated sustained ventricular tachycardia. 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.

Expiration dating for this device has been established and approved at 13 months.

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 or implantable cardioverter-defibrillator (ICD), 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 number of returned devices, with a breakdown into the number currently in analysis, the number operating properly, and the number failed (with the failure mechanisms described). Also 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 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.

4. The number of pulse generators returned to the applicant for cause from domestic sources, with a breakdown into the number currently in analysis, the number operating properly, and the number at normal battery depletion and failed (with the failure mechanisms described).
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. CDRH will notify the public of its decision to approve your PMA by making available, among other information, a summary of the safety and effectiveness data upon which the approval is based. The information can be

found on the FDA CDRH Internet HomePage located at www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/default.htm. Written requests for this information can also be made to the Dockets Management Branch, (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. The written request should include the PMA number or docket number. Within 30 days from the date that this information is placed on the Internet, any interested person may seek review of this decision by submitting a petition for review under section 515(g) of the act and requesting either a hearing or review by an independent advisory committee. FDA may, for good cause, extend this 30-day filing period.

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

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

Sincerely yours,

(b) (6)

~~(b) (6)~~ Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health