Inspections, Compliance, Enforcement, and Criminal Investigations

ELA Medical S.A.S 11/6/09

Department of Health and Human Services

Public Health Service
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

NOV 6 2009

WARNING LETTER

VIA FEDERAL EXPRESS AND FACSIMILE

Mr. Stefano Di Lullo
President, Sorin CRM Business Unit
ELA Medical S.A.S
98-100 Rue Maurice Arnoux
Montrouge, 92120, France

Dear Mr. Di Lullo:

During an inspection of your firm located in Montrouge, France on June 22 through June 25, 2009, an investigator from the United States Food and Drug Administration (FDA) determined that your firm manufactures the Ovatio 6750 Implantable Cardioverter Defibrillator (ICD). Under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 321(h), these products are devices because they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or are intended to affect the structure or function of the body.

Our inspection also revealed that your Ovatio 6750 ICD with CRT and Situs OTW Lead devices are misbranded under section 502(t)(2) of the Act, 21 U.S.C. 352(t)(2), in that your firm failed or refused to furnish material or information respecting the devices that is required by or under section 519 of the Act, 21 U.S.C. 360i, and Title 21, Code of Federal Regulations (C.F.R.), Part 803 - Medical Device Reporting (MDR) regulation. Significant deviations include, but are not limited to, the following:

1. Failure to report to the FDA no later than 30 calendar days after the day that your firm received or otherwise became aware of information, from any source, that reasonably suggests that your marketed device may have caused or contributed to a death or serious injury, as required by 21 C.F.R. § 803.50(a)(I). For example:

a. Complaint No. **(b)(4)** was received by your firm on May 29, 2008, from France, for the Ovatio CRT 6750 **(b)(6)** The complaint indicates that the ICD was incapable of delivering shock during induction attempt of the ventricular fibrillation and that the patient was treated with external electrical shock.

b. Complaint No. **(b)(4)** was received by your firm on February 18, 2009, from Toledo, Ohio, for the Ovatio ICD 6550 **(b)(6)** The complaint indicates that the ICD failed to charge during implantation procedure and the patient received external shock.

We have reviewed your response and have concluded that it does not appear to be adequate with respect to submitting reports under the Medical Device Reporting (MDR) regulation for adverse events that occur outside the United States (OUS). The MDR regulation applies to foreign manufacturers whose devices are in commercial distribution in the US. An adverse event that occurs overseas is reportable under the MDR regulation if the device is one that has been cleared for marketing in the US. Events that occur in other countries that involve a device that is also marketed in the us could have a significant bearing on our ability to recognize and act upon an impending public health issue in this country.

2. Failure to submit in your MDR to FDA all information required in Subpart E that was reasonably known to you, as required by 21 C.F.R. § 803.50 (b)(1)(ii) and 21 C.F.R. § 803.50 (b)(1)(iii).

For example, your complaint files for complaints **(b)(4)** and **(b)(4)** contained additional information that was not provided to FDA in the MDR reports submitted as MDR # 9610579-2009-00018 and MDR # 9610579-2009-00019, respectively, including the patient needed external shock as a result of the reported device failures and the analysis and your conclusions about the testing
conducted on the devices for each complaint.

We have reviewed your response and have concluded that it does not appear to be adequate because, although your firm submitted the two MDRs in response to the investigator's observations, your firm failed to report all information in your possession about the events.

3. Failure to develop, maintain, and implement written MDR procedures for internal systems that provide for timely and effective identification, communication, and evaluation of events that may be subject to MDR requirements, as required by 21 C.F.R. § 803.17.

For example, ELA Medical's Medical Device Reporting procedure states: "For events

occurring in the United States all complaints are reviewed for possible Medical Device Reporting by ELA Medical, Inc. which is the entity for filing Medical Device Reports (MDRs) for devices used in the United States." Adverse events occurring OUS are not reported to the FDA. Your firm lacks an effective identification of OUS events that may be subject to MDR requirements.

We have reviewed your response and have concluded that it does not appear to be adequate with respect to submitting reports under the Medical Device Reporting (MDR) regulation for adverse events that occur OUS. As stated above, the MDR regulation applies to foreign manufacturers whose devices are in commercial distribution in the US. An adverse event that occurs overseas is reportable under the MDR regulation if the device is one that has been cleared for marketing in the US.

In addition, FDA has noted nonconformances with regards to section 501(h) of the Act, 21 U.S.C. § 351(h), due to deficiencies of the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation found at 21 C.F.R. Part 820. These deviations include, but are not limited 10, the following:

1. Failure to adequately ensure that when the results of a process cannot be fully verified by subsequent inspection and test that the process shall be validated with a high degree of assurance and approved according to established procedure, as required by 21 C.F.R. 820.75(a). For example, on Page 25 of the **(b)(4)** Qualification Report, your firm states that the **(b)(4)** and that the operational qualification (OQ) result does "not conform with the expected result."

Your firm conducted Risk Analysis **(b)(4)** and concluded that the impact on device safety and effectiveness is critical to the extent that the "device is unable to deliver shock and may cause patient's death by lack of therapy" and the probability of occurrence is "improbable" or "incredible." Based on Risk Analysis **(b)(4)** your firm concluded that the validation criteria have been met and that the cleaning process for the **(b)(4)** is validated. The risk analysis does not mitigate the fact that the cleaning process is not capable and that it was not validated with a high degree of assurance. Although your firm performs a **(b)(4)** visual inspection after cleaning on all hybrid modules, there is no evidence to show that your firm modified the process, design, or equipment to address the failures observed during the OQ.

Your response dated July 10, 2009, does not appear to be adequate because it did not contain documentation showing implementation of the correction.

You should take prompt action to correct the violations addressed in this letter. Failure to promptly correct these violations may result in regulatory action, which may include detaining your devices without physical examination upon entry into the United States until the corrections are completed. Section 801(a) of the Act, 21 U.S.C. § 381(a). Also, U.S. federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, premarket approval applications for Class III devices to which the Please notify this office in writing within fifteen (15) working days from the date you receive this letter of the specific steps you have taken to correct the noted violations, including an explanation of how you plan to prevent these violations, or similar violations, from occurring again. Include documentation of the corrective action you have taken. If your

planned corrections will occur over time, please include a timetable for implementation of those corrections. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. If the documentation is not in English, please provide a translation to facilitate our review.

Your response should be sent to Michelle Noonan-Smith, Acting Branch Chief, Cardiac Rhythm and Electrophysiology Devices Branch, 10903 New Hampshire Avenue, Silver Spring, MD, 20903. If you have any questions about the content of this letter please contact Katherine Williams at (301)796-5578.

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your facility. It is your responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violations noted in this letter and in the Inspectional Observations, Form FDA 483 (FDA 483), issued at the closeout of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality assurance systems. You should investigate and determine the causes of the violations, and take prompt actions to correct the violations and to bring your products into compliance.

Sincerely yours,

/S/
Timothy A. Ulatowski

Director
Office of Compliance
Center for Devices and
Radiological Health