S 08-5C

DEPARTMENT OF HEALTH AND HUMAN SERVICE

Food and Drug Administration
New Orleans District
404 BNA Drive
Building 200, Suite 500
Nashville, TN 37217

Telephone: (615) 366-7801
FAX: (615) 366-7802

June 25, 2008

WARNING LETTER NO. 2008-NOL-17

FEDERAL EXPRESS
Delivery Signature Requested

Peter Baird, President
Encore Medical, LP
9800 Metric Boulevard
Austin, Texas 78758

Dear Mr. Baird:

During an inspection of your firm, Encore Medical, LP, dba Chattanooga Group, located at 4717 Adams Road, Hixson, Tennessee, on January 8 – 11, 2008, an investigator from the United States Food and Drug Administration (FDA) determined your firm manufactures muscle stimulators and ultrasound devices. Under Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 United States Code 321(h) (21 USC 321), 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.

This inspection revealed these devices are adulterated within the meaning of Section 501(h) of the Act [21 USC 351(h)], because the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System regulation found at Title 21, *Code of Federal Regulations*, Part 820 (21 CFR 820). We received a response letter from [redacted], dated January 23, 2008, concerning our investigator's observations noted on the Form FDA 483, List of Inspectional Observations, issued to Mr. Scott A. Klosterman, President. We address this response below, in relation to each of the noted violations. These violations include, but are not limited to, the following:

1. Failure to establish and maintain adequate procedures to identify actions(s) needed to correct and prevent recurrence of nonconforming product and other quality problems, as required by 21 CFR 820.100(a)(3). For example, your firm failed to identify the action(s) needed to correct failures and prevent additional failures for the following:

a. During the period May 2006 through December 2007, your firm received 64 complaints of either shock and/or burns to patients caused by a transient over-voltage malfunction in the Stim boards used in your muscle stimulator EPR product line. You received 58 of these complaints after you identified the malfunction in January 2007. Although you developed software versions to detect the over-voltage and cause the device to shut down, you installed the revision only in muscle stimulators in stock or returned from the complainants. The software revisions were not installed in devices in distribution channels. In addition, you received 50 complaints of shock or burns caused by muscle stimulators in the market after you identified a correction in March 2007.

b. In 2005, you became aware of a malfunction in which diodes were failing on the PCB US Gen boards used to control all ultrasound devices in your Vectra Genisys product line. You modified [redacted] boards which were in stock at your facility at this time. You did not replace the diodes in Ultrasound devices in distribution channels. Approximately [redacted] were returned and replaced by your firm from January 2007 to December 2007 despite having identified a correction in 2005. Furthermore, during the inspection, you failed to provide the investigator with written documentation of your CAPA activities regarding the ultrasound devices, as required by 21 CFR 820.100(a)(3) and 21 CFR 820.100(b).

Your firm's response is only partially adequate in addressing these violations. We acknowledge you have revised your written Corrective and Preventative Action (CAPA) procedures and provided written documentation for Corrective Action #1551. We acknowledge you recalled the muscle stimulators to install Software [redacted] in those devices. According to information your firm provided to FDA, the software revisions have been implemented to prevent a [redacted] from shorting. In addition, we acknowledge you have recalled your ultrasound devices from distribution channels because of high rates of diode failure.

Although your firm has begun to address FDA's concerns, you have not provided verification and validation data to demonstrate the software revision will be effective over the life of the device. In your response to this warning letter, please provide the verification and validation plans and reports for Software [redacted].

In addition, our inspection revealed your devices are misbranded under Section 502(t)(2) of the Act, 21 USC 352(t)(2), because your firm failed or refused to furnish material or information respecting the device required by or under Section 519 of the Act, 21 USC 360(i), and 21 CFR 803 – Medical Device Reporting (MDR) regulation. Significant deviations include, but are not limited to, the following:

1. Failure to submit MDR reports to FDA within 30 days of receiving or otherwise becoming aware of information that reasonably suggests a marketed device has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur, as required by 21 CFR 803.50(a)(2). Specifically, your firm failed to submit MDR reports for the following complaints concerning device malfunctions where transient over-voltage within the circuitry caused components to fail, resulting in a shock, burn, or high

output to the patient. These complaints were not reported as MDRs, despite your firm having become aware on July 6, 2007, of a serious burn injury that resulted from the same failure mode.

- One complaint regarding model 2760; Complaint Number 7362;
- Three complaints regarding model 2761; Complaint Numbers 7430, 7345, 7396;
- One complaint regarding model 2770; Complaint Number 7380;
- 10 complaints regarding model 2777; Complaint Numbers 7415, 7418, 7420, 7423, 7386, 7359, 7364, 7373, 7399, 7412;
- 13 complaints regarding model 2778; Complaint Numbers 7417, 7432, 7433, 7434, 7335, 7382, 7383, 7357, 7394, 7400, 7401, 7407, 7445;
- One complaint regarding model 2787; Complaint Number 7346;
- Six complaints regarding model 2788; Complaint Numbers 7411, 7385, 7384, 7379, 7344, 7439;
- Three complaints regarding model 2789; Complaint Numbers 7336, 7349, 7350;
- 10 complaints regarding model 2762CC; Complaint Numbers 7410, 7426, 7369, 7371, 7402, 7370, 7376, 7388, 7390, 7436;
- Nine complaints regarding model 2772MC; Complaint Numbers 7431, 7299, 7366, 7368, 7365, 7377, 7387, 7395, 7403;
- Three complaints regarding model 2773MS; Complaint Numbers 7424, 7378, 7372;
- One complaint regarding model 2752CC; Complaint Number 7428;
- One complaint regarding model INT002; Complaint Number 7446; and,
- One complaint regarding model INTCB; Complaint Number 7449.

2. During our post-inspection review of individual medical device manufacturer reports submitted per FDA Form 3500A, we noted several reports did not correctly indicate the type of reportable event in Block H, as required by 21 CFR 803.52(f)(1). In addition, reports failed to include all information which was reasonably known to the manufacturer, as required by 21 CFR 803.50(b)(1).

   For example, MDRs 1022819-2007-00001 and 1022819-2007-00002 involved a serious injury, which means an injury or illness: (1) is life-threatening; (2) results in permanent impairment of a body function or permanent damage to a body structure; or, (3) necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure (see 21 CFR 803.3). However, you reported these MDRs as malfunctions rather than serious injuries, and failed to include information such as:

   - For 1022819-2007-00001 – The patient received a burn that blistered and turned black. The patient visited a dermatologist, who prescribed medication to treat the injury. Further, the patient's skin was sufficiently damaged to such a degree that skin grafts were under consideration for a complete recovery without scarring. This event represents a serious injury because medical intervention was necessary to prevent permanent damage to a body structure.

- For 1022819-2007-00002 – The patient received a shock which provoked a panic attack. The MDR failed to indicate the patient screamed, panted, mumbled incoherently, and eventually became unresponsive. EMS/911 was called to take the patient by ambulance to the hospital. This event represents a serious injury because medical intervention was necessary to revive the patient.

Your firm's response is only partially adequate in addressing these violations. Before the close of the inspection, your firm submitted 15 MDR's to FDA for complaints of user shock or burning due to malfunctions of your muscle stimulators that occurred between July 17 and October 5, 2007. We acknowledge you amended your MDR standard operating procedure [redacted] retrained personnel, reviewed complaints using revised [redacted] and submitted three new MDRs to FDA.

However, you did not submit MDR's for 48 other similar complaints received prior to July 17, 2007. Those complaints must be filed as MDR's because your firm is in possession of information which reasonably suggests those malfunctions would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

You should take prompt action to correct the violations addressed in this letter. Failure to promptly correct these violations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil money penalties. Also, federal agencies are advised of the issuance of all warning letters concerning devices so they may take this information into account when considering the award of contracts. Additionally, premarket approval applications for Class III devices to which the Quality System regulation deviations are reasonably related will not be approved until the violations have been corrected. Requests for Certificates to Foreign Governments will not be granted until the violations related to the subject devices have been corrected.

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 violation(s), from recurring. 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.

Your response should be sent to U.S. Food and Drug Administration, Attention: Mark W. Rivero, Compliance Officer at the above address. If you have any questions about the content of this letter, please contact Mr. Rivero at (504) 219-8818 x 103.

This letter is not intended to be an all-inclusive list of 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 Form FDA 483, issued at the conclusion 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 bring your products into compliance.

Sincerely,

H. Tyler Thornburg
District Director
New Orleans District

Enclosure: Form FDA 483

cc: Scott A. Klosterman, President
Chattanooga Group
4717 Adams Road
Hixson, Tennessee 37343