DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 587-7500
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June 29, 2012

Glenda Crookes
Interim Executive Director
The Judge Rotenberg Educational Center
240 Turnpike Street
Canton, Massachusetts 02021-2359

Dear Ms. Crookes:

On November 9, 2010, through November 23, 2010, the U.S. Food and Drug Administration (FDA) inspected your manufacturing facility located at 240 Turnpike Street, Canton, MA. As a result of this inspection, we sent a letter to your firm dated May 23, 2011 indicating your GED3A and GED4 devices are adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. 351(f)(1)(B), because you do not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. 360e(a), or an approved application for an investigational device exemption (IDE) under section 520(g) of the Act, 21 U.S.C. 360j(g). Our letter also described serious problems with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation found at Title 21, Code of Federal Regulations (21 CFR), Part 820 and the Medical Device Reporting regulation found at 21 CFR Part 803. On July 13, 2011, a Regulatory Meeting was held at our office to discuss these deficiencies. During this meeting, we discussed the need for your firm to come into compliance as soon as possible.

We are in receipt of eleven (11) responses that were in response to our May 23, 2011 letter. These were dated July 21, 2011, September 14, 2011, October 14, 2011, November 15, 2011, December 15, 2011, January 20, 2012, February 24, 2012, March 20, 2012, April 17, 2012, May 11, 2012 and June 15, 2012. The FDA has completed our evaluation of your firm's corrections and corrective actions and provide our responses below.

Premarket Notification:

Our May 23, 2011 letter indicated that your organization has significantly changed or modified the Graduated Electronic Decelerators (GED) devices since obtaining initial FDA clearance on December 5, 1994 (K911820). We have reviewed your firm's responses to our letter and conclude that they are not adequate. (b) (4)
(b) (4)

In your responses, dated July 21, 2011 and September 14, 2011, your firm requested enforcement discretion which would allow the continued use of the GED3 and GED4 devices until a new 510(k) has cleared. We have reviewed your response dated July 21, 2011, and determined that your responses are not adequate. Your firm has not provided: 1) sufficient evidence to support the safety and effectiveness of these devices for treating aggressive behavior; 2) sufficient documentation to adequately characterize the output of the GED4 device and to determine the stimulation received by a patient; and 3) any information regarding the physical and/or psychological consequences of a student being placed in a pseudo restraint via the holster. Based on the inadequacy of the documentation provided in your responses, we disagree that enforcement discretion should be applied in this circumstance.

Your responses have indicated that a 510(k) notice for the GED3A and GED4 devices and its accessories was being prepared (b) (4)

GMP's

We have reviewed all of your responses that addressed the GMP observations noted in our May 23, 2011 letter. We acknowledge that your firm has hired (b) (4) as a third party design, development and manufacturing firm and that they will be manufacturing these devices for your facility in the near future. We note that your responses have not yet addressed the following items.

- Your firm has not provided design validation procedures to demonstrate the device conforms to defined user needs or its intended use.
- Your firm has not provided evidence of how the final release specifications for the GED3 or GED4 were determined or how the specifications relate to the final acceptance criteria for these devices.
- Your firm has not provided acceptance criteria for the GED devices in your DHR (QMS-007).
- Your firm has not provided a list of specific design input requirements in your Design Control Program (Document No. QMS-015). You have provided a general listing of design input requirements but does not list any specific design input requirements.
- Your firm has not provided: 1) a listing of all of the documents that encompass its QMS; 2) documentation regarding the review of the QMS for implementation of the Document Control (QMS-003); and 3) documentation indicating that all uncontrolled or obsolete quality system documents are no longer in use.
- Your firm has not provided a Device Master Record.

Please keep in mind that during a reinspection of your facility, we will need to verify that you are in compliance with all applicable regulations.

MDR's

Your responses were reviewed by FDA's Office of Surveillance and Biometrics (OSB). Upon review of your September 14, 2011 response, we acknowledge that your firm revised its MDR procedure to remove outdated references. However, your firm also removed information from its original procedure that should have remained in place. As such, the document now fails to meet the requirements of 21 CFR 803.17. The revised MDR procedure titled Medical Device Reporting, Doc: REG-001, Rev. A, effective: 09/12/11 does not meet the requirements of 21 CFR 803.17.

The following issues were noted in the revised MDR procedure:

1. REG-001, does not describe an internal system that provides for a standardized review process or procedure for determining when an event meets the criteria for reporting under this part. For example, there are no instructions for conducting a complete investigation of each event and evaluating the cause of the event.

2. REG-001, does not describe an internal process that provide for timely transmission of complete medical device reports to FDA. For example, there are no instructions for how to obtain and complete the FDA Form 3500A. The address identifying where MDR reports should be submitted is not included in the procedure. The address for MDR submission is: FDA, CDRH, Medical Device Reporting, P.O. Box 3002, Rockville, MD 20847-3002.

In addition, Attachment 1 titled "Medical Device Reporting Decision Tree" is not readable as the print is very small. It is recommended that your firm revise Attachment 1 to make it readable for the user.

Additionally, the adequacy of your response dated November 15, 2011, cannot be determined at this time. The information provided in Attachment 14 included a spreadsheet with limited information for the complaints received. Your firm stated that it received a complaint referencing a second degree burn for which "first aid was applied." Your firm determined that the event was not reportable. Without additional information from clarifying what type of "first aid was applied" to the patient, it cannot be determined whether the application of first aid to a second degree burn represents medical intervention necessary to preclude permanent impairment of a body function or permanent damage to a body structure and therefore cannot at this time determine if your assessment of reportability is correct.

If your firm wishes to submit MDR reports via electronic submission it can follow the directions stated at the following URL:

http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm107903.htm

If your firm wishes to discuss MDR reportability criteria or to schedule further communications, it may contact the MDR Policy Branch at 301-796-6670 or by email at MDRPolicy@fda.hhs.gov.

Please be advised that it is your firm's responsibility to assure compliance with the Federal Food, Drug, and Cosmetic Act and its implementing regulations or with other relevant legal authority.

We request that you provide us with an additional written response within 30 business days from the date you receive this letter.

Your firm's additional response should be sent to: Karen Archdeacon, Compliance Officer, Food and Drug Administration, One Montvale Avenue, 4th Floor, Stoneham, Massachusetts 02180. If you have any questions about the content of this letter, please contact: Karen Archdeacon at (781) 587-7491.

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

Sincerely yours,

Mutahar S. Shamsi
Director
New England District

Cc: (b) (4)
Robert Duquette, Judge Rotenberg Educational Center