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

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NWE-05-11

VIA UPS Next Day Air

May 23, 2011

Dr. Matthew Israel
Executive Director
The Judge Rotenberg Educational Center.
240 Turnpike Street
Canton, MA 02021 -2359

Dear Dr. Israel:

During an inspection of your firm located in Canton, MA on November 9, 2010, through November 23, 2010, investigators from the United States Food and Drug Administration (FDA) determined that your firm manufactures Graduated Electronic Decelerators (GED) devices, models GED3A and GED4. 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.

A review of our records indicates that we cleared a premarket notification (510(k)), K911820, for a GED device on December 5, 1994, with the following indication: "GED is indicated for the treatment of patients, usually diagnosed as retarded or autistic, who exhibit self-injurious behavior of sufficient intensity and frequency to cause serious damage to themselves. The device should be used only on patients where alternate forms of therapy have been attempted and failed."

In 2000, our office told you that the Judge Rotenberg Center and its GED devices were exempt from the 510(k) requirement pursuant to 21 CFR 807.65(d). We have learned that this is not accurate. While licensed practitioners are exempt from this requirement in certain circumstances, the exemptions at 21 U.S.C. 360(g) and 21 CFR 807.65 only apply to classes of *persons*, and do not exempt the *device* from applicable clearance and approval requirements. Since the devices that you manufacture are not within a type that is 510(k)-exempt, see 21 U.S.C. 360(*l*) and (m), they are subject to FDA clearance and approval requirements.

This inspection revealed that your organization has significantly changed or modified the GED device since obtaining clearance. The following constitute significant changes or modifications that require a premarket notification:

(1) As described on the device label for the GED3A and GED4, you have modified the intended use of the device by adding "severe behavior problems" to the indications. The term "severe behavior problems" signifies a new patient population that is not included in the cleared indications and that raises new questions of safety and effectiveness since it is not clear that this type of behavior would respond similarly to this intervention.

(2) The GED4 has a significantly higher device output than the cleared device. Specifically, our investigator obtained from your firm, "Safety Assessment of the GED Device," which indicates that current output (b) (4) load. Another document obtained from your firm, "Memo to File, Re. GED 3A and GED-4", indicates that the GED4 outpu(b) (4) load. The current output of the GED4 raises concerns of tissue heating and burns, and requires clinical data to validate the safety and effectiveness of this change.

(3) The "Safety Assessment of the GED Device" indicates that you have introduced two automated features to the GED3A and GED4 that were not part of the cleared device: (a) an automated stimulus when the patient removes either hand from their hip-holsters, and (b) a seat board that initiates a stimulus if the patient stands from their chair. These automated features could significantly affect the safety or effectiveness of the device and requires clinical data to evaluate.

These constitute significant changes or modifications that require a new premarket notification under 21 CFR 807.81(a)(3). As a result, the 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). The kind of information you need to submit in order to obtain approval or clearance for your device is described on the Internet at http://www.fda.gov/cdrh/devadvice/3122.html. The FDA will evaluate the information you submit and decide whether your product may be legally marketed.

Our inspection also revealed that these devices are adulterated within the meaning of section 501(h) of the Act (21 U.S.C. § 351(h)), in that 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 (QS) regulation found at Title 21, Code of Federal Regulations (C.F.R.), Part 820. These violations include, but are not limited to, the following:

1. Failure to establish and maintain procedures for validating the device design, as required by 21 CFR 820.30(g).

For example, when management representatives for your firm were asked if a validation plan had been created for the GED4 device, the representatives stated that it had not been created. Design Validation for the GED4 was not completed.

2. Failure to establish and maintain adequate procedures for finished device acceptance to ensure that each production run, lot, or batch of finished devices meets acceptance criteria and failure to document acceptance activities required by this part, as required by 21 CFR 820.80(d) and (e). For example,

   a. When management representatives for your firm were asked for the quality acceptance test specifications, final testing instructions, repair or test procedures, calibration procedures, and final acceptance criteria for the GED4 device, the representatives stated that these documents did not exist. Acceptance limits for the GED4 device are not specified in the Device History Record (DHR).

   b. Section 3.0 of the GED3A Test Procedure, ELEC-WI 013 REV C, dated 11/18/99, requires that the therapy voltage remain between (b) (4) of 13 DHRs for the GED3A lists the voltage as approximately equal to (b) (4) Additionally, GED3A unit # (b) (4) was released on 7/5/06. The test data associated with the DHR for this device, however, is dated 9/28/06, 2½ months after final release.

3. Failure to establish and maintain a Design History File (DHF) for each type of device that contains or references the records necessary to demonstrate that the design was developed in accordance with the approved design plan and the requirements of this part, as required by 21 CFR 820.30(j).

   For example, the DHF for the GED4 device was not available at the time of the inspection. When management representatives for your firm were asked for the DHF, the representatives stated that it did not exist.

4. Failure to designate an individual(s) to review for adequacy and approve prior to issuance of all documents established to meet the requirements of this part, as required by 21 CFR 820.40(a).

   For example, the GED3A Test Procedure, ELEC-WI 013 REV C, dated 11/18/99, which defines the procedure your firm shall use for the testing of the GED3A system, has not been signed and is, therefore, an uncontrolled document. Additionally, MFGINST-001, Rev. 7.0 Manufacturing Instructions for GED3A; ELEC-WI 005 REV 3, dated 8/8/00, Manufacturing for GED-3A; ELEC-0011 REV F, dated 3/03/10, GED Calibration; ELEC-0013 REV A, dated 2/24/97, Procedure for Medical Device Reporting; and ELEC-WI 0010 REV A, dated 6/4/99, Verification and Validation Plan are unsigned as well.

5. Failure to maintain adequate device master records (DMRs), as required by 21 CFR 820.181.

For example, the DMR for the GED3A device does not identify the Manufacturing Instructions, MFGINST-001, Rev 7.0. Additionally, the DMR for the GED4 device does not identify the manufacturing procedures, test procedures, or quality assurance procedures and acceptance criteria for the device.

We received your response dated December 3, 2010, concerning our investigator's observations noted on the Form FDA 483, List of Inspectional Observations that was issued to you. Your response is not adequate because:

1. You did not provide evidence of implementation of design verification and design validation procedures for the GED4.

2. You did not provide documentation of evidence that you reviewed all DHRs for each lot of the GED3A and GED4 devices to ensure that the acceptance criteria were met and that the devices should have been released according to your procedure.

3. You did not provide documentation of design reviews of the GED4 as part of the DHF to ensure the DHF for the GED4 is complete.

4. You did not provide evidence of implementation of a DMR for the GED4 device.

Our inspection also revealed that your GED3A and GED4 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 device that is required by or under section 519 of the Act, 21 U.S.C. 360i, and 21 CFR Part 803 - Medical Device Reporting (MDR) regulation. Significant violations include, but are not limited to, the following:

Failure to adequately 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 CFR Part 803.17(a)(1).

For example, your procedure includes numerous outdated references that demonstrates your procedure has not been updated as necessary to comply with current regulations. These outdated references do not ensure timely and effective communication of events that may be subject to MDR requirements.

You did not address this in your response dated December 3, 2010.

If you wish to discuss any concerns related to 21 CFR 803, you may contact the MDR Policy Branch, formerly the Reporting Systems Monitoring Branch, at 301-796-6670 or by email at RSMB@fda.hhs.gov.

Please notify this office in writing within thirty (30) 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 violation(s), or similar violation(s), from occurring again. Include documentation of the corrections and/or corrective actions you have taken. If

your planned corrections and/or corrective actions will occur over time, please include a timetable for implementation of these activities. If corrections and/or corrective actions cannot be completed within 30 working days, state the reason for the delay and the time within which these activities will be completed.

Your 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.

In addition, we have scheduled a meeting at New England District Office on July 13, 2011 to discuss this letter and your proposed corrections and/or corrective actions. Please notify Ms. Archdeacon at the above number to confirm this date or to reschedule a mutually convenient time.

Finally, you should know that this letter is not intended to be an all-inclusive list of the violation(s) at your facility. It is your responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violation(s) 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 violation(s), and take prompt actions to correct the violation(s) and to bring your products into compliance.

Sincerely yours,

Mutahar S. Shamsi
District Director
New England District