DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
One Montvale Avenue Stoneham, MA 02180 (781) 587-7500 Fax:(781) 587-7556 Industry Information: www.fda.gov/oc/industry	10/03/2012 - 10/17/2012* FEI NUMBER 1000120805

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Glenda P. Crookes, Executive Director

FIRM NAME	STREET ADDRESS
The Judge Rotenberg Educational Center, Inc.	250 Turnpike St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Canton, MA 02021-2359	Medical Device

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Procedures for design validation have not been adequately established.

Specifically, your quality manager stated that the designs of your graduated electronic decelerator (GED) devices models GED3A and GED4 have not been validated. No design validation report was available in the design history file for these models. Data is not available to demonstrate that the devices meet user needs and intended uses.

OBSERVATION 2

The design history file does not demonstrate that the design was developed following the requirements of 21 CFR 820.

Specifically, the design history files for the GED3A and GED4 are incomplete. For example, the design inputs document provided for both models entitled (b) (4) [redacted], is in draft form and does not reference the GED4.

OBSERVATION 3

Premarket clearance or approval was not obtained prior to implementing significant changes to a medical device.

Specifically, on 5/23/11 your firm was notified by FDA that your Graduated Electronic Decelerator (GED) devices models GED3A and GED4 have not been approved or cleared by FDA. Your firm continues to maintain the GED3A and GED4

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Maura Rooney, Investigator	10/17/2012

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devices and use them on clients for aversive behavioral therapy. On October 3, 2012 you provided a report from your GED tracking database showing (b)(4) clients were wearing a total of (b)(4) GED3A devices and (b)(4) clients were wearing a total of (b)(4) GED4 devices. The labels of your GED3A and GED4 devices continue to state that the device is intended for "severe behavior problems", and the GED4 continues to be operated at a significantly higher output (b)(4) than the cleared device.

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Observation Annotations

Observations intentionally left blank.

*** DATES OF INSPECTION:**
10/03/2012(Wed), 10/04/2012(Thu), 10/10/2012(Wed), 10/17/2012(Wed)

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	Maura Rooney, Investigator	10/17/2012