DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 W. Jackson Blvd., Suite 1500 Chicago, IL 60661-4716 (312) 353-5863 Fax:(312) 596-4187 Industry Information: www.fda.gov/oc/industry	01/18/2012 - 01/25/2012* FEI NUMBER 1420295

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Mr. David L Mirkovich, General Manager/ Sales Manager

FIRM NAME	STREET ADDRESS
Somatics, LLC	910 Sherwood Dr Ste 23
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Lake Bluff, IL 60044-2233	Manufacturer/ Specifications Developer

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 firm's Design Control procedure SOP-0401 has not been adequately established to ensure that design validation is performed on initial production units, lots, batches, or their equivalents. Additionally, your firm's Design Control procedure has not been adequately established to ensure that design changes are validated to conform to defined user needs and intended use of the device. This includes testing of production units under actual or simulated use conditions.

OBSERVATION 2

The results of design validation, including method(s), the date, and the individual(s) performing validation, were not documented in the design history file.

Specifically,

Your firm has not documented the results of the design validation for the Thymapad™ stimulus electrode to include the methods, the date, and the individual(s) performing the validation, in the design history file. For example, since January 2008, your firm has made changes to the wire profile inside the Thymapad™ stimulus electrode.

- revision two dated 1/08, indicates to "reduce size of wire fan"
- revision four dated 3/10, indicates "no more fanning of wire"
- revision five dated 3/11, indicates "increased the wire profile inside the electrode to lower immediate current density within the electrode".

AMENDMENT 1

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	Rafael Padilla, Investigator	01/25/2012

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There is no documentation in the design history file of the design validation to ensure the device conforms to the defined user needs and intended uses.

OBSERVATION 3

The written MDR Procedure does not include an internal system which provides for the timely and effective identification, communication, and evaluation of events that may be subject to medical device reporting requirements.

Specifically,

Your firm's MDR Procedure SOP-1403 Vigillance and Recall does not include an internal system which provides for the timely and effective identification, communication and evaluation of events that may be subject to medical device reporting requirements.

OBSERVATION 4

Procedures for receiving, reviewing, and evaluating complaints by a formally designated unit have not been adequately established.

Specifically,

Your firm's procedure SOP-1402 Post-Market Communication and Changes is not adequately established so that complaints are processed in a uniform and timely manner, oral complaints are documented upon receipt, and that complaints are evaluated for MDR reportability.

OBSERVATION 5

Records of complaint investigations do not include required information.

Specifically,

Your firm's complaint investigations do not include the nature and details of the complaint or any reply to the complainant. For example,

- report log number 110451 documented on your firm's Customer Inquiry/Complaint Form for a Thymatron® system states in the inquiry details "complaining about output, too much energy- not enough energy".
- report log number 111731 documented on your firm's Customer Inquiry/Complaint Form for a Thymatron® system

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states in the inquiry details "multiple complaints-treating & monitoring".

- report log number 112371 documented on your firm's Customer Inquiry/Complaint Form for a Thymatron® system states in the inquiry details "Doctor had multiple complaints over the last several months".

The investigations do not provide nature and details of the complaints and whether the device was being used to treat a patient. According to your firm's Sales Manager, most of the complaints for the Thymatron® system are associated to some type of issue, real or perceived encountered during treatment of a patient. Additionally your firm does not document any reply to the complainant.

OBSERVATION 6

Procedures for acceptance of incoming product have not been adequately established.

Specifically,

Your firm has not adequately established procedures for the acceptance of incoming product to include the documented acceptance or rejection activities of incoming product.

OBSERVATION 7

There is no agreement with suppliers to notify you of changes in the product or service.

Specifically,

Your firm does not have an agreement with the suppliers of the Thymapad™ stimulus electrode and the EEDS snap recording electrodes to notify you of any changes in the product or service so that your firm may determine whether the changes may affect the quality of the finished device.

OBSERVATION 8

Acceptance activities were not adequately documented.

Specifically,

~~Records for the~~

~~T~~Records for the acceptance activities of the Thymatron®, EEDS recording electrodes, and the Thymapad™ stimulus electrodes are not adequately documented to include the acceptance activities performed and the signature of the Individual(s) conducting the acceptance activities and where appropriate the equipment.

AMENDMENT 1

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Pl. 108_3

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OBSERVATION 9

Procedures have not been adequately established to control product that does not conform to specified requirements.

Specifically,

Your firm's Nonconforming Material procedure SOP-1301 does not include how nonconformances will be handled to address the documentation and evaluation of the nonconformance to include a determination for the need for an investigation of the nonconformance.

OBSERVATION 10

Procedures to ensure sampling methods are adequate for their intended use have not been established.

Specifically,

Your firm's incoming acceptance activities for the Thymapad™ stimulus electrodes and EEDS recording electrodes requires samples to be inspected from each incoming shipment of product regardless of lot size. Your firm's procedure SOP-2001 Statistical Techniques does not ensure sampling methods are adequate for their intended use.

OBSERVATION 11

Procedures for identifying valid statistical techniques required for establishing, controlling, and verifying the acceptability of process capability and product characteristics have not been adequately established.

Specifically,

Your firm's procedure SOP-2001 Statistical Techniques does not identifying a valid statistical technique for controlling and verifying product characteristics of incoming product and supplies as well as your firm's use of statistics to evaluate complaints associated to a product line or lot of product.

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Observation Annotations

Observation 1:	Promised to correct.	Observation 2:	Promised to correct.
Observation 3:	Promised to correct.	Observation 4:	Promised to correct.
Observation 5:	Promised to correct.	Observation 6:	Promised to correct.
Observation 7:	Promised to correct.	Observation 8:	Promised to correct.
Observation 9:	Promised to correct.	Observation 10:	Promised to correct.
Observation 11:	Promised to correct.		

*** DATES OF INSPECTION:**
01/18/2012(Wed), 01/24/2012(Tue), 01/25/2012(Wed)

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Non-Printing Observations

OBSERVATION 1

Devices for which listing is required have not been listed.

Specifically,

Your firm has not submitted device listings with the specific product codes for the following medical devices: MouthGuard/ Ventil-A™ Mouth Protector and Thymapad™ stimulus electrode/ EEDS recording electrodes.