Food and Drug Administration
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To: DAVID MIRKOVICH	**From:** R. KEVIN VOGEL
Fax: (847) 234-6763	**Pages:** 4 + COVER
Phone:	**Date:** 4/22/16
Re:	**CC:**

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• **Comments:**

THIS IS THE FDA-483 INSPECTIONAL OBSERVATIONS FORM WE DISCUSSED EARLIER TODAY.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderly Place, Suite 200 Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768	4/20/2016-4/22/2016
	FEI NUMBER 1420295

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
David (nmi) Mirkovich , General Manager

FIRM NAME	STREET ADDRESS
Somatics, LLC	720 Commerce Dr Unit 101
CITY, STATE, ZIP CODE, COUNTRY Venice, FL 34292-1750	TYPE ESTABLISHMENT INSPECTED Medical Device Specification 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 to ensure that all purchased or otherwise received product and services conform to specified requirements have not been adequately established.

Firm's Supplier Evaluation and Monitoring QSP 7.4-1 Rev 1 dated 2/24/2014 is inadequate in that there is no requirement for firm to obtain documented evidence that its critical suppliers have proper controls for critical operations including but not limited to process validation of special and automated processes, purchasing controls, environmental controls such as ESD (Electrostatic Discharge) Controls, or software development/software validation such as structural and functional testing.

OBSERVATION 2

Procedures for finished device acceptance have not been adequately established.

Firm's final acceptance of its Thymatron devices does not include test of alarm, heart rate monitoring, or EEG (seizure) monitoring.

OBSERVATION 3

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

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Richard K Vogel, Investigator X Richard K Vogel Richard K Vogel Investigator Signed by: Richard K Vogel-S	4/22/2016

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Firm added 0.25 msec Ultrabrief pulsewidth feature on 8/1/2001 in version 5.20 of Thymatron software. Firm added EEG Frequency Messures (Interictal Frontal Delta Analysis) on 11/15/2002 in version 5.40 of Thymatron software. Firm did not have Design History File for these changes including but not limited to assessment for the need for regulatory requirments {510(k)}.

OBSERVATION 4

Results of the design risk analysis were not adequately documented.

Firm's Risk Analysis Report 7.3-3-2 Rev 1 dated 3/29/2016 for Thymatron device is inadequate in that:
(A) It lacks risk of burns and risk of memory loss.
(B) It lacks risks related to heart rate monitoring or EEG (seizure) monitoring.
(C) It lacks process related risks.

OBSERVATION 5

Procedures to ensure equipment is routinely calibrated have not been established.

Calibration of test equipment used during final acceptance test of Thymatron devices is done once a year by firm's contract manufacturer, but this is not documented.

OBSERVATION 6

Procedures for design change have not been adequately established.

Firm does not require all design changes to be done in accordance with appropriate sections of design control section of the Quality System regulation.

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Annotations to Observations

Observation 1: Not annotated
Observation 2: Not annotated
Observation 3: Not annotated
Observation 4: Not annotated
Observation 5: Not annotated
Observation 6: Not annotated

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."