DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407) 475-4700 Fax:(407) 475-4768 Industry Information: www.fda.gov/oc/industry	01/12/2009 - 01/13/2009
	FEI NUMBER 3005893178

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Robert A. Bessner, Chief Executive Officer

FIRM NAME	STREET ADDRESS
TiTERA SAGE, LLC. RKV ~~Sage Corporation~~	21000 Boca Rio Rd Ste A21c
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Boca Raton, FL 33433-1551	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

The design history file was not established or maintained.

Firm lacks design history files including the review for the need for 510(k) submission.

OBSERVATION 2

Procedures to control the design process of the device were not established, defined, documented, and implemented.

OBSERVATION 3

Procedures to ensure that all purchased or otherwise received product and services conform to specified requirements were not established, defined, documented, and implemented.

OBSERVATION 4

Records of complaint investigations do not include the results of the investigation.

Firm fails to document nature and detailsof complaint, the results of investigation, and any corrective action.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Richard K Vogel, Investigator Richard K. Vogel	01/13/2009

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OBSERVATION 5

The procedures for implementing corrective and preventive actions were not established, defined, documented, and implemented.

OBSERVATION 6

Quality audits were not conducted to verify that the quality system is effective in fulfilling your quality system objectives.

Firm has failed to conduct internal audits and lacks internal audit procedure.

OBSERVATION 7

Written MDR procedures have not been developed.

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Observation Annotations

Observations intentionally left blank.

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