DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Avenue Silver Spring, MD 20993 (301) 594-4695 Fax:(301) 594-4715 Industry Information: www.fda.gov/oc/industry	12/10/2015 - 12/18/2015* FEI NUMBER 3007967308

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Dr. Rick E. Harrison, MD,, Chief Medical Officer

FIRM NAME	STREET ADDRESS
UCLA Ronald Reagan Medical Center	757 Westwood Plz
CITY, STATE, ZIP CODE, COUNTRY	**TYPE ESTABLISHMENT INSPECTED**
Los Angeles, CA 90095-8358	User facility (Hospital)

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 user facility failed to provide all information concerning individual adverse event reports that is reasonably known to them, including information found in documents in possession of the user facility.

Specifically, a medical device complaint was submitted under MAUDE (Manufacturer and User Facility Device Experience), Report Date: b(3) ,Event Date: b(3) b(6) Report Number: b(3) in which the report included information where there was a total of (b patients involved (all involved reportable cases) . The user facility did not file separately each of the (b)(3) additional individual adverse events.

OBSERVATION 2

The user facility did not submit FDA Form 3500A or electronic equivalent to the known device manufacturer within 10 working days of becoming aware of information that reasonably suggests that a device has or may have caused or contributed to a serious injury to a patient of the facility.

Specifically, a MedSun Report submitted and dated: b(3) with an event date: b(3) b(6) (Report Name: b(3) involved a device that malfunctioned and caused an intervention to prevent permanent impairment or damage to the patient. This report was not submitted within required timeframes.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Juanita Banuelos, Investigator Juanita Banuelos	12/18/2015

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Observation Annotations

Observation 1: Under consideration.

Observation 2: Promised to correct.

*** DATES OF INSPECTION:**
12/10/2015(Thu), 12/14/2015(Mon), 12/18/2015(Fri)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Juanita Banuelos, Investigator	12/18/2015