DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612 949-608-2900	12/01/2015 – 12/07/2015
	FEI NUMBER 3000717534

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Ms. Colleen M. Collar, Director, Office of Licensure, Accreditation, and Regulatory (OLAR)

FIRM NAME	STREET ADDRESS
Cedars-Sinai Medical Center	8700 Beverly Boulevard
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Los Angeles, CA 90048	User Facility

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.

DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

1. Written MDR procedures have not been developed. Specifically, your two paged written MDR procedure, entitled "Biomedical Equipment Safe Medical Device Act", dated 07/22/2010, does not address or refer to the following elements:

   A) The use of FDA Form 3500A or electronic equivalent for mandatory device adverse event reporting.

   B) The definition of a serious injury.

   C) Your user facility reporting number.

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 in the facility. Specifically, you submitted on (b)(3) [redacted] a voluntary FDA form 3500 for an event, dated (b)(3), (b)(6) [redacted] where a device malfunctioned and caused an intervention to prevent permanent impairment or damage to the patient. You did not identify this event with your user facility reporting number.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
	James R. Fleckenstein	James R. Fleckenstein, Investigator	12/07/2015