

**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION**

DISTRICT OFFICE ADDRESS AND PHONE NUMBER  
19701 Fairchild  
Irvine, CA 92612  
949-608-2900

DATE(S) OF INSPECTION  
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  
Cedars-Sinai Medical Center

STREET ADDRESS  
8700 Beverly Boulevard

CITY, STATE AND ZIP CODE  
Los Angeles, CA 90048

TYPE OF ESTABLISHMENT INSPECTED  
User Facility

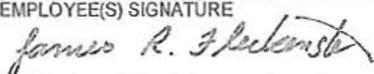
THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OBSERVATIONS, AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AN OBJECTION REGARDING AN OBSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO 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) a voluntary FDA form 3500 for an event, dated (b)(3), (b)(6) 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) James R. Fleckenstein, Investigator	DATE ISSUED 12/07/2015
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