DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612 (949) 608-2900 Fax:(949) 608-4417 Industry Information: www.fda.gov/oc/industry	12/08/2015 - 12/11/2015 FEI NUMBER 2080950

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Farnaz (NMI) Datomi, Director, Risk Services

FIRM NAME	STREET ADDRESS
Huntington Memorial Hospital	100 W California Blvd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Pasadena, CA 91105-3010	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.

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 did not submit FDA Form 3500A or electronic equivalent to FDA and the device manufacturer within ten working days after becoming aware of information that reasonably suggests that a device has or may have caused or contributed to the death of a patient of the facility.

Specifically,

A) Medical Device Report (MDR) b(3) was submitted to the FDA and the manufacturer, on b(3) for one of three patients with (b)(3) acquired following (b)(3) (b)(3) performed using (b)(3) This MDR was marked "Adverse Event" with no other outcomes listed. However, review of the patient's records revealed that the patient had expired on b(6) with the primary diagnosis listed as multiorgan failure due to (b)(3) caused by (b)(3) (b)(3) Furthermore, the report was submitted on (b)(3) but the MDR event file shows you became aware of the event on b(3)

B) Medical records for an (b) (6) patient indicate the patient expired, on b(6) after sepsis due to multidrug-resistant pseudomonas and cardiac arrest, following an endoscopic retrograde cholangiopancreatograms (ERCP) procedure. On b(6) your facility became aware of additional bacterial DNA fingerprinting results that show this patient's infection was probably related to 14 other confirmed cases of multidrug-resistant pseudomonas infections caused by contaminated duodenoscopes used during ERCP procedures. However, this death was not reported to the FDA and the manufacturer by your facility.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Janet Pulver, Investigator	12/11/2015

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 judgement, 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."

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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, Medical Device Reports (MDRs b(3) nd b(3) were submitted to the FDA and the manufacturer for two patients with (b)(3) acquired following (b)(3) (b)(3) Your facility became aware of these events on b(3) and b(3) respectively; however, the MDRs were not sent to the FDA and manufacturer until b(3)

OBSERVATION 3

Written MDR procedures have not been implemented.

Specifically, the Medical Device Reporting Program procedure (Policy #117, dated 5/2013) requires your facility to establish and maintain MDR event files (Incident Files). On 11/10/15, your facility became aware of DNA fingerprinting test results that show 11 cases of multidrug-resistant pseudomonas patient infections were likely related to contaminated duodenoscopes used in endoscopic retrograde cholangiopancreatogram (ERCP) procedures. However, these events were not documented in your Incident Reporting system, Incident Reports were not initiated, and no records were maintained documenting the deliberations and decision making processes used to determine whether these potentially device-related infections were reportable to the FDA.

For example, MDR event files were not initiated, and MDR reportability determination was not documented, for the following events which required medical intervention to treat the infections:

- (b) (6) had a peripherally inserted central catheter (PICC) placed with intravenous (IV) antibiotics
- (b) (6) administered additional IV antibiotics
- (b) (6) required long-term antibiotics (including IV)

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Observation Annotations

Observations intentionally left blank.

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AMENDMENT 1

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