DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax:(313)393-8139	12/15/2015-2/3/2016* FEI NUMBER 3004492321

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Lisa A. Sorenson , Executive Director of Accreditation and Surveys

FIRM NAME	STREET ADDRESS
Indiana University Hospital	550 University Blvd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Indianapolis, IN 46202-5149	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 written MDR Procedure does not include an internal system which provides for the timely and effective identification , communication and evaluation of events that may be subject to medical device reporting requirements.

Specifically, your facility's Safe Medical Devices, policy #EC 4.04 approved 4/30/2013, Patient Incident and Significant Event Management, policy #ADM 1.51 approved 5/31/2012, and Sentinel and Adverse Event Management, policy #RM 1.01 approved 2/28/2014, procedures are inadequate in that:

1. Adverse events involving the use of a medical device that may have caused or contributed to the death of a patient were not reported to the FDA and the device manufacturer via a MedWatch 3500A form within ten (10) working days of being identified. On b(3) , your facility initiated a retrospective review of cases involving the use of b(3) and subsequently identified that two (2) patients had contracted a b(3) b(3) infection that resulted in complications which may have potentially led to the deaths of those patients. Your facility could not provide documentation showing that Medical Device Reports were submitted to the FDA and device manufacturer for these incidents.
2. Adverse events involving the use of a medical device that may have caused or contributed to the serious injury of a patient were not reported to the FDA via a MedWatch 3500A form within ten (10) working days of being identified. Your firm utilizes the NCC MERP Index for Categorizing Medication Errors to determine when events involving patient harm occur. The Index classifies Categories E through H as resulting in patient harm and, in the timeframe from 1/1/2014 to

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Joseph R Strelnik, Investigator 2/3/2016 X Joseph R Strelnik Joseph R Strelnik Investigator Signed by: Joseph R. Strelnik -S	2/3/2016

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12/15/2015, your facility has documented twelve (12) incidents that were classified as Category E, indicating "an error occurred that may have contributed to or resulted in temporary harm to the patient and required intervention." Your facility has no documentation of Medical Device Reports being submitted to the device manufacturers for these incidents.

3. The procedures do not include provisions for:
    a. Reporting adverse events via the mandatory Medwatch 3500A form to the FDA or device manufacturers. During the inspection, your organization's personnel stated that your policy is to report all adverse events via the voluntary reporting Medwatch portal. However, your facility has not maintained documentation that would serve as objective evidence of this activity.
    b. Including required information that is reasonably known to your facility in a Medical Device Report to the FDA or device manufacturer. This information would include: Patient information, adverse event information, device information, initial reporter information, and user facility information.

OBSERVATION 2

MDR event files have not been established and maintained.

Specifically, your facility has not established and maintained MDR event files to include:

1. Copies or references for:
    a. All information that is reasonably known to your facility regarding potentially reportable adverse events.
    b. All information that is utilized in the evaluation of potentially reportable adverse events.
2. The decisions for whether or not an adverse event must be reported to the FDA or medical device manufacturer via Medwatch Form 3500A.

Annotations to Observations

Observation 1: Promised to correct
Observation 2: Promised to correct

***DATES OF INSPECTION**

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12/15/2015(Tue),1/28/2016(Thu),2/03/2016(Wed)

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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 judgment, 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."