DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Customhouse Rm900 2nd & Chestnut St Philadelphia, PA 19106 (215)597-4390 Ext:4200 Fax:(215)597-0875	12/8/2015-12/16/2015* FEI NUMBER 2571104

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
David A Schlappy , Vice President

FIRM NAME	STREET ADDRESS
The Reading Hospital and Medical Center	6th Ave&Spruce St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
West Reading, PA 19611	Medical Device 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 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, the hospital became aware of an adverse event on b(3), resulting from the use of a b(3) during a surgical b(3) performed on b(3) b(3). The patient later developed b(3) and died in the hospital on b(6). The hospital failed to submit FDA Form 3500A within ten working days to the FDA and the device manufacturer.

OBSERVATION 2

The user facility did not submit FDA Form 3500A or electronic equivalent to the 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, FDA Form 3500A, UF/Importer Report # b(3) Adverse Event dated b(3), resulted in permanent impairment to a patient was submitted to the FDA on b(3) outside the 10 day reporting requirement. Additionally, the report was not filed with the manufacturer nor were there documents/records indicating the manufacturer was notified of the adverse event.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Edward D Mcdonald, Investigator 12/16/2015 X Edward D Mcdonald Edward D Mcdonald Investigator Signed by: Edward D Mcdonald -S	12/16/2015

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OBSERVATION 3

The written MDR procedure does not include an internal system which provides for a standardized review process/procedure for determining when an event meets the criteria for reporting.

Specifically, the established procedure, Administrative Policy and Procedure, No.10.56, Revised: February 2004, does not provide formal standardized criteria for determining if an adverse event is reportable.

OBSERVATION 4

The written MDR procedure does not include documentation and recordkeeping requirements for all information that was evaluated to determine if an event was reportable.

Specifically, Administrative Policy and Procedure No. 10.56, Medical Device Reporting System, Revised: February 2004, does not include a written procedure for documenting and record keeping requirements for all information evaluated to determine if an event was reportable.

OBSERVATION 5

MDR event files have not been established and maintained.

Specifically, MDR event files have not been established and maintained for the following adverse events:

a. FDA Form 3500A UF/Importer Report # b(3) , dated b(3)

Annotations to Observations

Observation 1: Not annotated
Observation 2: Not annotated
Observation 3: Not annotated

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Observation 4: Not annotated
Observation 5: Not annotated

***DATES OF INSPECTION**
12/08/2015(Tue),12/10/2015(Thu),12/16/2015(Wed)

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	Edward D Mcdonald, Investigator 12/16/2015 X Edward D Mcdonald Edward D Mcdonald Investigator Signed by: Edward D Mcdonald -S	12/16/2015

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 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."