DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Ave. Jamaica, NY 11433 (718) 340-7000 Fax:(718) 662-5661 Industry Information: www.fda.gov/oc/industry	12/07/2015 - 12/10/2015* FEI NUMBER 1000521590

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Mary Simmerling, Vice President of Quality and Patient Safety

FIRM NAME	STREET ADDRESS
New York Presbyterian Hospital	525 East 68th Street
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
New York, NY 10021	User Facility/Hospital

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 WE OBSERVED:

OBSERVATION 1

The user facility did not submit FDA Form 3500A or electronic equivalent to FDA 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, your hospital discovered in early May of b(3) that b(3) patients who underwent b(3) b(3) procedures performed from b(3) with the use of the b(3) devices used in your hospital developed b(3) infections. These b(3) cases were reported to the FDA as one MDR event on b(3). Upon further review 3 of these patients expired.

OBSERVATION 2

Written MDR procedures have not been developed, maintained, and implemented.

Specifically, your hospital has not developed, maintained, or implemented MDR procedures which state that a report must be submitted to the FDA no more than 10 working days after the day that you become aware of information from any source, that reasonably suggests that a device has or may have caused or contributed to the death of a patient of your facility. The MDR procedure must also state the form which must be used in order to submit an MDR to the FDA.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Andrew Garufi, Investigator Ronald Ifraimov, Investigator	12/10/2015

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 Annotations

Observations intentionally left blank.

*** DATES OF INSPECTION:**
12/07/2015(Mon), 12/08/2015(Tue), 12/10/2015(Thu)

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