DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
One Montvale Avenue Stoneham, MA 02180 (781)587-7500 Fax:(781)587-7556	12/7/2015-12/10/2015* FEI NUMBER 3012030543

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Susan W. Wante , Director of Risk Management

FIRM NAME	STREET ADDRESS
Brigham and Women's Hospital	75 Francis St, Device User Facility
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Boston, MA 02115-6110	Hospital/ 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, on or about b(3) b(6) Brigham and Woman's hospital became aware of a patient death associated with a previous b(3) model # b(3) Serial # b(3) b(6) procedure at this facility. This event was not reported to FDA.

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, review of 48 Medical Device Reports (MDRs) submitted by Brigham and Women's Hospital through MedSun from January 1, 2014 through December 9, 2015 revealed four MDRs submitted more than 10 working days after the date of event.

MedSun report #	Date of Event	Date of Report
b(3)	b(3)	b(3)

AMENDMENT 1

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Stephen C Smith, Investigator
Sherry K. Markwell -S
12/29/2015
X Stephen C Smith
Stephen C Smith
Investigator
Signed by: Stephen C. Smith -S

DATE ISSUED
12/29/2015

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b(3) b(3) b(3) b(3) b(3) b(3)

OBSERVATION 3

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

Specifically, External Regulatory Reporting of Adverse Events, Policy Number: 5.4.7, Date 8/15, section 3. FDA states, "Under the Safe Medical Devices Act of 1990, the FDA mandates reporting of any serious patient injury or death that is caused by a medical device within 10 days of discovery of the event. The Department of Risk Management is responsible for this reporting function through MedSun online reporting system." The Director of Risk Management stated that these two sentences are the hospitals only written procedure covering MDR reporting for FDA.

OBSERVATION 4

MDR event files have not been established and maintained.

Specifically, I requested MDR event files related to death or serious injury. Director of Risk Management stated that the hospital does not maintain files other than what is reported through MedSun. Required information such as records of deliberations and decision making processes used to determine whether a death or serious injury was or was not reportable was not available for inspection.

Annotations to Observations

Observation 1:	Under consideration
Observation 2:	Promised to correct
Observation 3:	Promised to correct
Observation 4:	Promised to correct

*DATES OF INSPECTION

12/07/2015(Mon),12/08/2015(Tue),12/10/2015(Thu)

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Stephen C Smith, Investigator Sherry K. Markwell -S 12/29/2015 X Stephen C Smith Stephen C Smith Investigator Signed by: Stephen C. Smith -S	12/29/2015

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."