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	12/15/2015-12/18/2015
	FEI NUMBER 1283713

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

John B. Belknap , Chief Compliance Officer

FIRM NAME	STREET ADDRESS
The General Hospital Corporation	55 Fruit St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Boston, MA 02114-2621	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 WE OBSERVED:

OBSERVATION 1

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

Specifically, the policies and procedures related to medical device reporting (including: (1) the *Quality and Patient Safety Plan*; (2) the *Clinical Manual Policy for Adverse Events and Medical Error*; and (3) the *Regulatory Agencies: Reportability Criteria*) do not address the following:

A. Timeframes for reporting medical device reports to manufacturers or to FDA.
B. Complete documentation and record keeping requirements for medical device reports.

OBSERVATION 2

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,

A. Draft MedSun report # b(3) not been submitted as of b(3) more than 18 months after the patient death on b(6) The event involved a patient in cardiac arrest in the emergency department with no b(3) .

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Elizabeth B Griffin, Engineer/Investigator Sherry K Markwell, Investigator 12/18/2015 X Elizabeth B Griffin Elizabeth B Griffin Engineer/Investigator Signed by: Elizabeth B. Griffin -S	12/18/2015

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
One Montvale Avenue Stoneham, MA 02180 (781)587-7500 Fax:(781)587-7556	12/15/2015-12/18/2015 FEI NUMBER 1283713

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
John B. Belknap , Chief Compliance Officer

FIRM NAME	STREET ADDRESS
The General Hospital Corporation	55 Fruit St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Boston, MA 02114-2621	User Facility

B. Draft MedSun report # b(3) has not been submitted as of b(3), more than ten months after determining on or about b(3)b(6) that the b(3) may have contributed to the patient's death on b(6).

C. MedSun report # b(3) was not submitted until b(3) (five days late), following a surgical procedure on b(3)b(6) involving the use of a b(3) which did not b(3). Additionally, the MedSun report listed the event as a serious injury, and did not include the information that the patient died on b(6)

D. MedSun report # b(3) was not submitted until b(3) (five days late), following a patient death on b(6). The event involved a surgical patient where it was found that a b(3) had fractured and approximately b(3) of the b(3) remained b(3). The patient was unable to be resuscitated.

OBSERVATION 3

The user facility did not submit FDA Form 3500A or electronic equivalent to the FDA, because the device manufacturer was unknown, 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,

A. Draft MedSun report # b(3) has not been submitted as of b(3) more than fourteen months after becoming aware on b(3) that a b(3) was retained in a patient following a surgical procedure on b(3) b(6) and had to be surgically removed.

B. MedSun report # b(3) was not submitted until b(3) more than five months after having to surgically remove a ruptured b(3) from a patient on b(3)b(6). Additionally, the MedSun report did not include the information that the event resulted in a b(3) for the patient on b(3).

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Elizabeth B Griffin, Engineer/Investigator Sherry K Markwell, Investigator 12/18/2015 X Elizabeth B Griffin Elizabeth B Griffin Engineer/Investigator Signed by: Elizabeth B. Griffin -S	12/18/2015

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
One Montvale Avenue Stoneham, MA 02180 (781)587-7500 Fax:(781)587-7556	12/15/2015-12/18/2015
	FEI NUMBER 1283713

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

John B. Belknap , Chief Compliance Officer

FIRM NAME	STREET ADDRESS
The General Hospital Corporation	55 Fruit St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Boston, MA 02114-2621	User Facility

OBSERVATION 4

MDR event files do not contain or reference all adverse event information in the possession of the reporting entity, including documentation of the deliberations and decision making process used to determine if an event was or was not reportable.

Specifically, hospital Medical Device Report (MDR) files consist only of MedSun reports; they do not include references to or copies of evaluations conducted by various hospital departments such as the Biomedical Engineering department, or root cause analyses as required by the *Adverse Events and Medical Error* policy, or determinations regarding reportability as required by the *Quality and Patient Safety Plan*.

Annotations to Observations

Observation 1:	Promised to correct
Observation 2:	Corrected and verified
Observation 3:	Corrected and verified
Observation 4:	Promised to correct

12/18/2015

X Sherry K Markwell

Sherry K Markwell
Investigator
Signed by: Sherry K. Markwell -S

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Elizabeth B Griffin, Engineer/Investigator Sherry K Markwell, Investigator	12/18/2015

12/18/2015
X Elizabeth B Griffin
Elizabeth B Griffin
Engineer/Investigator
Signed by: Elizabeth B. Griffin -S

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."