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	12/9/2015-12/11/2015
	FEI NUMBER 3004123934

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Margaret M. Hudlin , Chief Medical Officer

FIRM NAME	STREET ADDRESS
Umass Memorial Medical Center	55 Lake Avenue North
CITY, STATE, ZIP CODE, COUNTRY Worcester, MA 01655-0002	TYPE ESTABLISHMENT INSPECTED 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 WE OBSERVED:

OBSERVATION 1

The written MDR Procedure does not include an internal system which provides for the timely and effective identification and communication and evaluation of events that may be subject to medical device reporting requirements.

Specifically,

A) Your hospital/user facility did not submit a Medical Device Report, within 10 working days of becoming aware of the b(3) incident (Incident number b(3)) of (b) patients that were infected with the same strain of b(3) and b(3) and found that b(3) were used on the (b) patients. Of these, 3 patients died (2 of the 3 patients had complicated illnesses).

B) Your hospital/user facility has not submitted a Medical Device Report within 10 working days of becoming aware of the b(3) incident (Incident Report Number b(3)) of an b(3) sustaining b(3) associated with a b(3) .

C) Timeframes for submitting MDR reports to FDA and manufacturers through Medsun are not defined in the Risk Management Procedure.

OBSERVATION 2

MDR event files have not been established and maintained.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jeffrey J Thibodeau, Investigator Sherry K Markwell, Investigator	12/11/2015 X Jeffrey J Thibodeau Jeffrey J Thibodeau Investigator Signed by: Jeffrey J. Thibodeau -S	12/11/2015

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Specifically,
Although your hospital/user facility participates in MedSun to submit Medical Device Reports to FDA and Manufacturers, your hospital/user facility has not established and maintained documentation used to determine if a device-related death, serious injury, or malfunction was or was not reportable. For example:
1. The hospital's incident reporting system is not linked to MDR files and patient records for compilation of data.
2. The decision making process for MDR reportability is not documented.
3. There is no corresponding business file to allow staff to easily identify and access corresponding information to MDRs.

OBSERVATION 3
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,
An event of life threatening serious injury occurred b(3) b(6) for rupture of the b(3) on the b(3) under Report b(3) and was submitted through MedSun on b(3), outside of the 10 working day requirement.

Annotations to Observations

Observation 1: Under consideration
Observation 2: Under consideration
Observation 3: Under consideration

12/11/2015
X Sherry K Markwell
Sherry K Markwell
Investigator
Signed by: Sherry K. Markwell -S

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Jeffrey J Thibodeau, Investigator Sherry K Markwell, Investigator	12/11/2015

12/11/2015
X Jeffrey J Thibodeau
Jeffrey J Thibodeau
Investigator
Signed by: Jeffrey J. Thibodeau -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."