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	12/16/2015-12/17/2015
	FEI NUMBER 3012030481

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
John D. Birkmeyer , Exec. VP, Integrated Delivery System

FIRM NAME	STREET ADDRESS
Dartmouth Hitchcock Medical Center	1 Medical Center Dr
CITY, STATE, ZIP CODE, COUNTRY Lebanon, NH 03756-1000	TYPE ESTABLISHMENT INSPECTED 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

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

Specifically, Medical Equipment Management Plan (MEMP) Policy - Clinical Engineering, Policy 4, Date: 12/15/98 through 10/28/14 and Medical Equipment Management Plan (MEMP) policy - Clinical Engineering, Policy ID: 6012, Date: 10/28/14 to present, are inadequate to insure a timely and effective identification, communication, and evaluation of events that may be subject to MDR requirements. The Department of Risk Management and Clinical Engineering are responsible for submitting Medical Device Reporting (MDR) Events to FDA through MedSun. The Risk Manager stated these are the only policies and procedures covering MDR submission 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, on or about b(3) , the hospital became aware of a b(3) b(3) (patient safety event ID: b(6)) that was used for a b(3) where the device was inserted with the b(3) side towards the inside of the vessel. This resulted in a b(3) and required further surgical intervention while still in operating room (OR). The hospital /user facility is required to submit to FDA (through MedSun), reports of serious injury that

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Abby E Pelletier, Investigator Stephen C Smith, Investigator Sherry K Markwell, 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

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reasonably suggest that a device has or may have caused or contributed serious injury. This event was not submitted to FDA/manufacturer through MedSun.

Specifically, on b(3) , a patient was on a b(3) that did not b(3) (Patient Safety Event ID: b(6) . Description in event stated, " b(3) " This event was not submitted to FDA/manufacturer through MedSun.

OBSERVATION 3

MDR event files have not been established and maintained.

Specifically, Risk Manager 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:	Promised to correct within 90 Days
Observation 2:	Promised to correct within 90 Days
Observation 3:	Promised to correct within 90 Days

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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."