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 ofb(3) more than 18 months after the patient death onb(6) The event involved a patient in cardiac arrest in the emergency department with no b(3).
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) and had to be surgically removed.

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

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<thead>
<tr>
<th>Observation</th>
<th>Action</th>
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<tbody>
<tr>
<td>1</td>
<td>Promised to correct</td>
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<tr>
<td>2</td>
<td>Corrected and verified</td>
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<tr>
<td>3</td>
<td>Corrected and verified</td>
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<tr>
<td>4</td>
<td>Promised to correct</td>
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12/18/2015

[X] Sherry K Markwell

Signed by: Sherry K Markwell

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**See Reverse of This Page**

Elizabeth B Griffin, Engineer/Investigator

Sherry K Markwell, Investigator

12/18/2015

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**FORM FDA 483 (09/08)**

PREVIOUS EDITION OBSOLETE

INSPECTIONAL OBSERVATIONS

PAGE 3 OF 3 PAGES
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."