DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Customhouse Rm900 2nd & Chestnut St Philadelphia, PA 19106 (215)597-4390 Ext:4200 Fax:(215)597-0875	12/3/2015-12/17/2015* FEI NUMBER 2521206

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Jane F. Collins, Director of Regulatory

FIRM NAME	STREET ADDRESS
Allegheny General Hospital	320 E North Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Pittsburgh, PA 15212-4756	Medical Device 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 I OBSERVED:

OBSERVATION 1

The user facility did not submit FDA Form 3500A or electronic equivalent to FDA and the device manufacturer 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, an FDA Form 3500A was never submitted to the known device manufacturer or to the FDA after becoming aware of information that reasonably suggests that a Duodenoscope and/or a central line contributed to a patient death. The patient b(6), with Medical Record b(6) underwent an ERCP procedure at another hospital and had positive CRE cultures at that facility. On b(6), the patient was admitted and was found to have positive blood and sputum cultures upon admission. The patient underwent an ERCP procedure on b(6), and had repeated, subsequent positive CRE cultures following this procedure. On (b) (6) negative blood cultures were taken, but on (b) (6), positive CRE blood cultures were again found. The patient died on b(6) This patient's "Infection Report", dated b(6) documents that the CRE infection found on (b) (6) was a hospital and central-line associated infection.

OBSERVATION 2

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Katelyn A. Staub-Zamperini, Investigator	12/17/2015

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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 FDA Form 3500A was never submitted to the known device manufacturer or to the FDA after becoming aware of information that reasonably suggests that a Duodenoscope contributed to a serious injury to a patient of the facility. The patient, b(6) with Medical Record b(6) underwent an EGD procedure using a Duodenoscope on b(6) and on (b) (6) bile cultures were found to be positive for "ESCHERICHIA COLI FEW Presumptive Carbapenemase producer Isolate", as well as abdomen and aspirate cultures taken on b(6)

OBSERVATION 3

Written MDR procedures have not been implemented .

Specifically, your "Safe Medical Device Act" medical device reporting procedure with Policy Manual No. 9018 has not been implemented. Furthermore, you have no documentation to show that all of the "Policy Guidelines" required per Policy Manual No. 9018 were followed or completed before or after you submitted Form FDA 3500 on b(3) to the manufacturer concerning the adverse event with patient # b(3)b(6) and Medical Record # b(3)b(6)

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.

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Jane F. Collins, Director of Regulatory	
FIRM NAME Allegheny General Hospital	STREET ADDRESS 320 E North Ave
CITY, STATE, ZIP CODE, COUNTRY Pittsburgh, PA 15212-4756	TYPE ESTABLISHMENT INSPECTED Medical Device User Facility/Hospital

Specifically, you have no documentation of the deliberations and decision making process used to determine if the death of E.M.F., with patient identifier 571824 and Medical Record # 00912139, was or was not reportable.

OBSERVATION 5

The user facility report submitted on FDA Form 3500A did not include all information reasonably known.

Specifically,

a) On b(3) you submitted FDA Form 3500 for voluntary reporting, to the medical device manufacturer due to a serious injury to a patient, instead of the required, FDA Form 3500A for mandatory reporting. The patient b(6) with patient identifier b(3) b(6) Medical Record # b(3) b(6) was admitted on b(3) b(6) and underwent an b(3) using a b(3) on the same day. Two days later on b(3), blood cultures were drawn which were found positive for b(3) b(3) Additional positive blood cultures were also drawn on subsequent days. On b(3), blood cultures were drawn, which were found to be negative for b(3) and the patient was discharged the next day on b(6) No bile or sputum cultures were taken. The patient died on an unknown date in b(6) at another facility, and your b(3) b(3)

b) The Form FDA 3500 you submitted to the medical device manufacturer on b(3) concerning patient b(3) b(6) and Medical Record # b(3) b(6) did not include all required information that was reasonably known to you at that time. The following information was reasonably known to you, but was not submitted at that time: patient weight, patient followup or required treatment, brand name, product code, model number, lot number or other identifying number of the associated medical device.

OBSERVATION 6

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The written MDR procedure does not include an internal system which provides for timely transmission of complete medical device reports to FDA and manufacturers.

Specifically, your "Safe Medical Device Act" medical device reporting procedure with Policy Manual No. 9018 does not specify that reports of death must be submitted to the FDA and the manufacturer, if known, and that reports of serious injury must be submitted to the manufacturer.

Annotations to Observations

Observation 1: Not annotated
Observation 2: Not annotated
Observation 3: Not annotated
Observation 4: Not annotated
Observation 5: Not annotated
Observation 6: Not annotated

***DATES OF INSPECTION**
12/03/2015(Thu),12/04/2015(Fri),12/07/2015(Mon),12/08/2015(Tue),12/17/2015(Thu)

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	Katelyn A. Staub-Zamperini, Investigator	12/17/2015

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."