DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6751 Steger Drive Cincinnati, OH 45237-3097 (513)679-2700 Fax:(513)679-2772	2/3/2016-2/9/2016* FEI NUMBER 1526801

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Theresa M. Myers , Manager, Regulatory Affairs/Quality Assurance

FIRM NAME	STREET ADDRESS
Fluke Biomedical LLC	6045 Cochran Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Solon, OH 44139-3303	Medical Device Manufacturer

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

Complaint files are not maintained. Specifically ***

Specifically,

Your firm is not capturing complaints regarding your CLEAR-Pb radiation shield products. A review of 8 RMAs (Return Material Authorizations) covering the past 3 years showed three instances which appear to meet the definition of a complaint yet no complaint files were opened.

OBSERVATION 2

A device history record has not been adequately maintained.

Specifically,

A review of 9 device history records (DHRs) covering the past year of shipments for your mobile radiation shield ((b) (4)) found your firm is not implementing your procedures/forms for device history records.

a) There is no documented release or QA review of product prior to shipment per SP-210-F2 "Device History Record Form".

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b) Non-conforming components are not linked to specific device history records therefore you cannot identify which devices were shipped with non-conforming components.

c) You do not document the results of inspection activities per QSP-210-F3 "Measurement Data Form".

d) Your testing specifications for components do not always match the drawing/specification for the component.

OBSERVATION 3

Potential suppliers , contractors and consultants were not evaluated and selected based on their ability to meet specified requirements.

Specifically, none of the five suppliers files for you CLEAR-Pb products show that the supplier was adequately selected.

Your Supplier Assessment Request form used to qualify suppliers does not capture quality system information to determine if the supplier has the ability to manufacture acceptable products. Four out of five suppliers used to manufacture the CLEAR- Pb product have no certification such as ISO and no documented evidence of an adequate quality system. Additionally, you have not determined whether these firms have validated and monitor processes regarding the manufacturing of your components.

Also, per your FBC supplier handbook, Rev 2., if a supplier is ISO certified they must submit a written copy of their quality manual which meets or exceeds requirements listed in the handbook. There is no quality manual in your supplier file for the one supplier that claimed ISO certification.

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Additionally, according to your FBC Supplier Handbook, Rev 2, supplier status (preferred, qualified, approved, disqualified) is supposed to be noted on approved supplier list (ASL). This was not done for any of your CLEAR- Pb suppliers.

OBSERVATION 4
Requirements that must be met by suppliers have not been established.

Specifically,

According to your Purchasing Procedure, QSP-206, Rev 20. If a supplier is given a quality rating lower than 80% for three consecutive months then you are to review the non-conformities, perform evaluations, communicate the results of the evaluations to the supplier and open a supplier corrective action (SCAR).

You have consistently assigned an unacceptable rating to (b) (4) (one of your five suppliers of the clear PB product) since at least March 2015 with no evidence of supplier communication or supplier corrective action request (SCAR).

OBSERVATION 5
Products that do not conform to specifications are not adequately controlled.

Specifically, your firm does not have an area to segregate and isolate non-conforming products. During this inspection, non-conforming product was found in the same area as released and un-inspected product.

Additionally, according to your Deviation Procedure, QSP-13-03, Rev 8. "A Deviation is a temporary or short-term approval of a change that is applied to a limited number of units or components". This

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inspection found that you have been creating temporary deviations for non-conforming product from the same supplier (b) (4)) since at least June of 2011.

Annotations to Observations

Observation 1: Reported corrected, not verified
Observation 2: Promised to correct
Observation 3: Promised to correct
Observation 4: Promised to correct
Observation 5: Promised to correct

***DATES OF INSPECTION**

2/03/2016(Wed),2/04/2016(Thu),2/05/2016(Fri),2/08/2016(Mon),2/09/2016(Tue)

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