**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
FOOD AND DRUG ADMINISTRATION

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 158-15 Liberty Avenue<br>Jamaica, NY 11433<br>(718) 340-7000 Ext:5301 Fax:(718)662-5661 | 5/23/2017-6/1/2017*<br>FEI NUMBER<br>3001451602 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

William J. Fox , Chief Technical Officer and Vice President Technical Operations

| FIRM NAME | STREET ADDRESS |
|---|---|
| Caliber Imaging and Diagnostics, Inc. | 50 Methodist Hill Drive, Suite 1000 |
| CITY, STATE, ZIP CODE, COUNTRY | TYPE ESTABLISHMENT INSPECTED |
| Rochester, NY 14623-2782 | 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

Validation of device software is inadequate.

Specifically, the software validation for an update to (b) (4) using software version Vivascan (b) (4), signed off on 9/1/16, had multiple sections that were either left blank or crossed out without any justification. Also, (b) (4) tests were noted to have failed, but no record of a defect report or of the tests being rerun were available as required by VivaScan Software Validation Plan, Master Control #04502, Rev. B. Additionally, every even numbered page of the validation was missing from the record and could not be located when requested.

## OBSERVATION 2

Software used as part of production has not been adequately validated for its intended use according to an established protocol.

Specifically, VivaScope (b) (4) - Design Description, dated January 28, 2013, was provided by the firm as the software validation for their (b) (4) test used as part of acceptance testing for the VivaScope 1500 and 3000. The document did not include a procedure for the validation and no other procedure for the software validation was available. Additionally, (b) (4) Validation, dated 10/24/16, had (b) (4) listed as skipped with no justification provided. In addition, step 16 for (b) (4) did not have clearly defined expected results.

AMENDMENT 1

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | DATE ISSUED |
|---|---|---|
| | Matthew D Schnittker, Investigator<br>Verifying...<br>X Matthew D Schnittker<br>Matthew D Schnittker<br>Investigator<br>Signed by: Matthew D. Schnittker -S | 6/1/2017 |

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**OBSERVATION 3**
Procedures for corrective and preventive action have not been adequately established.

Specifically, (b)( of 12 CAPAs reviewed were not verified or validated as effective and to not adversely affect the finished device. Additionally, the firm's Corrective and Preventative Action Procedure, Doc Number 00237, Revision M does not include a requirement to verify or validate corrective actions to ensure they do not cause any adverse effects.

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**OBSERVATION 4**
Procedures for design verification have not been adequately established.

Specifically, Record (b) (4) is listed on VivaScope 3000 Product Trace Matrix, Doc Number 03945, Revision C as the verification results for requirements (b) (4) . Neither this document, nor the DHF, included the method used for the verification.

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**Annotations to Observations**

Observation 1: Promised to correct
Observation 2: Promised to correct
Observation 3: Promised to correct
Observation 4: Promised to correct

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***DATES OF INSPECTION**
5/23/2017(Tue),5/24/2017(Wed),5/25/2017(Thu),5/30/2017(Tue),6/01/2017(Thu)

AMENDMENT 1

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