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

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 1431 Harbor Bay Parkway<br>Alameda, CA 94502-7070<br>(510) 337-6700 Fax:(510) 337-6702<br>Industry Information: www.fda.gov/oc/industry | 08/25/2015 - 09/16/2015*<br>FEI NUMBER<br>3010479366 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

**TO:** Elizabeth A. Holmes, Chief Executive Officer and Founder

| FIRM NAME | STREET ADDRESS |
|---|---|
| Theranos, Inc. | 1701 Page Mill Road |
| CITY, STATE, ZIP CODE, COUNTRY | TYPE ESTABLISHMENT INSPECTED |
| Palo Alto, CA 94304-1111 | 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 WE OBSERVED:**

## OBSERVATION 1

Design validation did not ensure the device conforms to defined user needs and intended uses.

Specifically,

You provided (b) (4) (b) (4) as evidence of design validation which was conducted in April 2014. The validation:

(b) (4)

(b) (4)

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|---|---|---|
| | Seema S. Singh, Investigator<br>Ian A. Pilcher, Investigator | 09/16/2015 |

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## OBSERVATION 2

The design was not validated under actual or simulated use conditions.

Specifically,

Your design validation plan (b) (4) provided as evidence of design validation, does not demonstrate that TSCD (b) (4) that were produced using the same specifications, production and (b) (4) procedures, and equipment that will be used for routine production. For example, you do not list or refer to the TSCD lot numbers used, specific instruments or analyzers used, documents with revisions numbers used, or the (b) (4) protocols used.

## OBSERVATION 3

Design input requirements were not adequately documented.

Specifically,

A. In your (b) (4) *Revision A*, you list (b) (4) '. However, in (b) (4) you do not list all the specific (b) (4) TSCDs are intended to be used with or the (b) (4) for each (b) (4) You have used the (b) (4) TSCD device to collect patient samples and have reported the results with at least (b) (4)

B. You (b) (4) either a (b) (4) to your TSCD device. You do not address the amount of (b) (4) in your design requirements or specifications document such that the device will perform to meet its intended use, specifically for th (b) (4) In your (b) (4) you (b) (4) (b) (4) (b) (4) (b) (4) TSCD device to collect patient samples and have reported the results with at least (b) (4)

## OBSERVATION 4

Results of the design risk analysis were not adequately documented.

Specifically,

A. You provide multiple assay results to patients using the TSCD devices (b) (4)

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(b) (4) However, you do not document the possible hazards associated with the TSCD design for (b) (4) (b) (4) DOC-0069 Revision A.

B. *DOC-0069 Revision A,* provided as the desig (b) (4) describes:

(b) (4)

(b) (4)

**OBSERVATION 5**

Documents were not reviewed and not approved by designated individual(s) prior to issuance .

Specifically,

A. (b) (4) DOC-0069 Revision A, provided as the hazard analysis for the (b) (4) devices, was utilized from February-April 2014. The document does not have an effective date. The document was not released in your document control system until 8/26/15 (during the inspection). The document was not reviewed and approved prior to 8/26/15.

B. There is no document number, revision or effective date for your design validation (b) (4) (b) (4) (b) (4) These documents were provided as evidence of design validation conducted in 2014; however, they were drafted during this inspection and were not reviewed and approved until 9/10/15.

C. There is no document number, revision or effective date for (b) (4) (b) (4) This document was provided as a follow-up to the failures in your design validation conducted in 2014; however, this document was drafted during the inspection. It has not been reviewed or approved until 9/10/15.

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**Observation Annotations**

| | | | |
|---|---|---|---|
| Observation 1: | Reported corrected, not verified. | Observation 2: | Reported corrected, not verified. |
| Observation 3: | Reported corrected, not verified. | Observation 4: | Reported corrected, not verified. |
| Observation 5: | Reported corrected, not verified. | | |

*** DATES OF INSPECTION:**
**08/25/2015(Tue), 08/26/2015(Wed), 08/27/2015(Thu), 08/28/2015(Fri), 09/01/2015(Tue), 09/02/2015(Wed), 09/03/2015(Thu), 09/04/2015(Fri), 09/09/2015(Wed), 09/10/2015(Thu), 09/11/2015(Fri), 09/16/2015(Wed)**

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