DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
404 BNA Dr., Bldg. 200, Ste. 500 Nashville, TN 37217-2597 (615)366-7801 Fax:(615)366-7802	10/17/2016-10/21/2016* FEI NUMBER 1037371

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Earl G. Anspach , Director of Production

FIRM NAME	STREET ADDRESS
Customer Service Associates, LLC	100 Wilton Circle
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Winchester, TN 37398-2504	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

Written MDR procedures have not been developed and maintained.

Specifically,

CSWI028, MDR Reporting (Rev. 0), describes your firm's process for Medical Device Reporting. This procedure fails to establish the following requirements:

- A process for timely and effective identification, communication, and evaluation of events that may be subject to MDR requirements;
- A process for how your firm will meet its requirements for the timely transmission of complete medical device reports to FDA; and
- Documentation and record-keeping requirements.

OBSERVATION 2

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

Specifically,

AMENDMENT 2

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Mary A Millner, Investigator 10/21/2016 X Mary A Millner Mary A Millner Investigator Signed by: Mary A. Millner -S	10/21/2016

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SOP015, Quality Planning (Rev. 4), does not clearly specify when quality issues identified from trended quality data will result in CAPA action. For example, between 05/18/2014 and 09/27/2016 your firm received 76 complaints related to the LC300-15 model blood pressure monitoring kiosk. Complaint investigations identified that 30 of these complaints were attributed to a cuff leak. Further investigation to the root cause of the cuff leaks was not elevated to a CAPA.

OBSERVATION 3

Procedures for receiving, reviewing, and evaluating complaints by a formally designated unit have not been adequately established.

Specifically,

SOP047, Complaint Files (Rev. 7), does not clearly direct employees to evaluate complaints with no or minor injuries for MDR reportability.

OBSERVATION 4

Procedures to control labeling activities have not been adequately established.

Specifically,

SOP034, Labeling and Packaging (Rev. 2), requires (b) (4)
(b) (4)
.
Of the 21 DHRs reviewed for the higi blood pressure monitoring kiosks (Model ZT2776-A00), none contained documentation of the inspection of the device labeling for accuracy or the final release of the device labeling.

OBSERVATION 5

A device history record has not been adequately maintained.

Specifically,

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Of the 21 DHRs reviewed for the higi blood pressure monitoring kiosks (Model ZT2776-A00), none included the primary identification label for the production unit. The DHRs only include the outer packaging label.

OBSERVATION 6

Procedures have not been adequately established to control product that does not conform to specified requirements.

Specifically,

SOP031, Control of Nonconforming Product (Rev. 2), does not specify where rework activities and subsequent inspection are documented. Review of the DHRs associated with four Nonconformance Reports (NCR 0109, NCR 0114, NCR 0133, and NCR 0126) found no documentation of rework activities.

OBSERVATION 7

A justification for not reporting the correction or removal action to FDA that included conclusions, follow-ups and reviews by a designated person was not included in the record.

Specifically,

You failed to maintain required records for a correction and removal action which was not required to be reported to FDA. In March 2015, you (b) (4) from (b) (4) blood pressure monitoring kiosks (Model ZT2776-A00), in commercial distribution due to a potential quality issue. Records of the action do not include the justification for not reporting the action to FDA.

Annotations to Observations

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

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Observation 4: Promised to correct
Observation 5: Promised to correct
Observation 6: Promised to correct
Observation 7: Promised to correct

***DATES OF INSPECTION**
10/17/2016(Mon),10/18/2016(Tue),10/19/2016(Wed),10/21/2016(Fri)

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