DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Drive, Suite 205 Lenexa, KS 66214 (913)495-5100 Fax:(913)495-5115	5/21/2018-5/24/2018
	FEI NUMBER 3003419114

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
John D. Hilburn, Plant Manager

FIRM NAME	STREET ADDRESS
American Contract Systems, Inc.	2610 Ne Industrial Dr Ste 220
CITY, STATE, ZIP CODE, COUNTRY Kansas City, MO 64117-2648	TYPE ESTABLISHMENT INSPECTED Contract Sterilizer, Manufacturer, Repackager/Relabeler

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

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

Specifically, Non-Conforming Product SOP, CP-04, Rev. 16, 10/20/2017, states under section 6.1.2.1, "An NCPR is required for any non-conforming material or assembly provided to, or subject to, the EO gas injection process. This includes any defect or deficiency involving the tray wrap, sterilization bag, EO gas delivery, bag sealing process, or aeration or sterility test conditions or results. The latter includes out-of-specification temperature conditions as shown on the recorder chart." Non-Conforming Product Reports have not been generated for bag sealing issues post gas injection or aeration chamber temperature excursions outside the specification range of (b) (4) degrees F.

OBSERVATION 2

Acceptance activities were not adequately documented.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Eric C Fox, Investigator	X Eric C Fox Investigator Signed By: 2001885254 Date Signed: 05-24-2018 10:35:25	5/24/2018

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Specifically, Product Release SOP, PR-01, Rev. 12, 11/03/2017, states under section 6.3, "Production records shall be reviewed to ensure that they are complete, accurate, and properly approved. The critical specifications below must be verified prior to releasing product. 6.3.1. Production Work Order Checklist, F-AS-01-3, was completed". The Production Work Order Checklist is being partially completed, signed and initialed prior to the assembly of the surgical kits and then scanned photocopies are generated. After the surgical kits are assembled, the pre-filled forms are dated and the Tray Number and Lot Number are documented.

OBSERVATION 3

Procedures for the acceptance of in-process product have not been adequately established.

Specifically, Assembly SOP, AS-01, Rev. 12, 06/05/2017, states under section 6.4.5, "Plant Manager or Assistant reviews the entire production work order record packet and, if complete and correct, approves the Production Work Order Checklist". The approval of the Production Work Order Checklist, F-AS-01-3, is being performed by employees other than the Plant Manager and Assistant Plant Manager.

OBSERVATION 4

Individuals who conduct quality audits have direct responsibility for the matters being audited.

Specifically, a consulting firm was contracted to submit electronic Medical Device Reports to the FDA on behalf of American Contract Systems, Inc. The consulting firm has performed an Internal Quality Audit of American Contract Systems, Inc.'s entire quality system.

OBSERVATION 5

The organizational structure has not been adequately established and maintained to ensure that devices are produced in accordance with 21 CFR 820.

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Specifically,

A. The appointment of a management representative who has authority over and responsibility for ensuring quality systems requirements are effectively established and maintained and reports on the performance of the quality system to management with executive responsibility through management review has not been documented.

B. Personnel independence for personnel who manage, perform, and assess work affecting quality has not been provided. The Plant Manager controls and oversees production and approves the final release of finished product.

OBSERVATION 6

A correction or removal, conducted to reduce a risk to health posed by a device, was not reported in writing to FDA.

Specifically, a recall was conducted for all surgical convenience kits which contained Powdered Surgical Gloves, a banned medical device, and a report was not submitted in writing to the FDA.

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Annotations to Observations

Observation 1:

Observation 2:

Observation 3:

Observation 4:

Observation 5:

Observation 6:

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