DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768	8/12/2019-8/16/2019
	FEI NUMBER 3003309947

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Srean S. Ly, Plant Manager

FIRM NAME	STREET ADDRESS
American Contract Systems, Inc.	7802 E. Telecom Pkwy.
CITY, STATE, ZIP CODE, COUNTRY Tampa, FL 33637	TYPE ESTABLISHMENT INSPECTED 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

A process whose results cannot be fully verified by subsequent inspection and test has not been adequately validated according to established procedures.

Specifically,

(A) Firm's test samples in (b) (4) and (b) (4) used in sterilization validations including the one in April 2019 for wrapped kits and tyvek pouch kits are not selected to assure all worse case conditions including but not limited to those components most likely to retain (b) (4), those that are worse case in terms of detrimental affect by the (b) (4), and (b) (4).

(B) Firm has no requirement for written assessment of existing/new components in kits in terms of worse case for difficulty of sterilization, difficulty in (b) (4) on component's material/functionality by American Contract Systems (ACS) (b) (4) (especially if subject component is originally labeled by (b) (4)'), and (b) (4) is required (if component is originally labeled by (b) (4) or it is (b) (4), etc.).

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	Richard K Vogel, Investigator X Richard K Vogel Investigator Signed By: Richard K. Vogel -S Date Signed: 08-16-2019 10:14:58	8/16/2019

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(C) Firm fails to include any process challenge device or other type of biological indicator inside packaging (either back table wrap or tyvek pouch) during sterilization validation.

(D) Firm fails to measure the (b) (4) during validation to assure consistency of dissipation and to substantiate (b) (4) for (b) (4)

(E) Firm's sterilization (b) (4) The sterilization validation protocol for wrapped kits and tyvek pouch kits does not assure worse case thickness bag is used in terms of minimum (b) (4) (in that it is only required to be less then 5.50 mils in protocols) or in terms of maximum (b) (4) (in that it is only required to be greater than 6.6 mils in protocols).

(F) (b) (4), however there is no tolerance identified and no worse case (b) (4) is included in firm's sterilization validations.

(G) Firm has not completed temperature distribution study with product present to assure temperature is consistent throughout rooms in which sterilization/aeration is completed.

(H) Firm's testing of (b) (4) does not include worse case lowest temperature in aeration room.

(I) Firm requires (b) (4) in breakdown and assembly areas, but no specification for preconditioning temperature and no documented explanation as to why it is not included.

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(J) Firm's SV-07 Sterilization Batch Validation Protocol Rev 00 dated 12/4/2018 was used to complete most recent validation of tyvek pouch kits. It is required to use (b) (4) 10 components in 6 tyvek packs in SB6 size sterilization bags. No deviation was documented.

OBSERVATION 2

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

Specifically,

Firm has failed to complete (b) (4) at the code level of software used to control the firm's (b) (4).

OBSERVATION 3

Procedures to ensure that all purchased or otherwise received product and services conform to specified requirements have not been adequately established.

Specifically,

Firm has failed to document adequate purchasing control for service providers such as software development/maintenance contractors in that no evidence of (b) (4) at the code level is required of software in (b) (4)) and no evidence of

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contractor's training to appropriate coding standards in regards to contractor's maintenance of (b) (4) software.

OBSERVATION 4

Results of the design risk analysis were not documented.

OBSERVATION 5

Procedures for design validation have not been established.

Specifically,

It is required in firm's AS-03 Labeling Procedure Rev 14 dated 8/9/2019 that sterile tray (kit) expiration date be labeled as the shorter of (1) Twelve months from production date and (2) The earliest component expiration date recorded on the Production Work Order form. Firm does not document determination if expiration date on subject component is for sterility purposes or to prevent component material or (b) (4) and further has no stability study requirement to substantiate the (b) (4) is still valid after component is subjected to the firm's (b) (4).

OBSERVATION 6

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

Specifically,

It is stated in firm's CH-01 Complaint Handling procedure Rev 13 dated 5/17/2019 the complaint investigation is intended to confirm the root cause or main contributing factors to the event. Firm received Complaint 19-026

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dated 2/14/2019 which references the balloon on the catheter was not deflating during the procedure. It is stated in firm's investigation they believe problem may have been vendor related, but firm failed to document determination that this catheter's balloon would not be affected by processes at (b) (4) process. In addition, the firm failed to document attempt to determine if the balloon failure resulted in the need for additional medical intervention to preclude serious injury or caused any substantial delay to the procedure.

OBSERVATION 7

Procedures for design control have not been established.

Specifically,

Firm lacks written Design Control procedure to cover any Class 2 or Unclassified Kits.

OBSERVATION 8

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

Specifically,

Firm's Corrective and Preventive Action (CAPA) procedure Rev 16 dated 3/15/2019 is inadequate in that:

(A) It does not clearly require every action meeting the definition of a CAPA to be verified or validated as effective and verified or validated that it does not adversely affect the finished device.

(B) No threshold is defined as to when CAPA is required to be initiated.

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Annotations to Observations

Observation 1:

Observation 2:

Observation 3:

Observation 4:

Observation 5:

Observation 6:

Observation 7:

Observation 8:

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."