

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER 550 Main Street, Ste 4-930 Cincinnati, OH 45202 (513) 322-0700 Fax: (513) 679-2772 oradevices1firmresponse@fda.hhs.gov		DATE(S) OF INSPECTION 8/5/2024-8/14/2024* FEI NUMBER 3008492337	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Eric B. Kuebler, Operations Manager			
FIRM NAME American Contract Systems Inc		STREET ADDRESS 85 Shaffer Park Dr	
CITY, STATE, ZIP CODE, COUNTRY Tiffin, OH 44883-9290		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.			
<i>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.</i>			
DURING AN INSPECTION OF YOUR FIRM WE OBSERVED: OBSERVATION 1 Procedures for acceptance of incoming product have not been adequately established. Specifically, your procedure number RV-01 "Receiving Procedure" revision 23, dated April 12, 2024 (and previous revisions 23 dated 12/05/2023 and revision 23 dated 1/22/2024) does not ensure that raw materials used in the sterilization of assembled kits are adequately controlled. For example, 1) In 8 out of 10 sterilization bag acceptance inspection records reviewed, at least one measurement was outside of assigned specifications for length, width, and/or thickness. The sterilization bags were still accepted for use by your firm. 2) Your firm did not ensure that the correct number of samples were reviewed during incoming acceptance. In 2 out of 10 sterilization bag acceptance inspection records reviewed, ^{(b) (4)} records were reviewed instead of the required ^{(b) (4)}.			
OBSERVATION 2 The organizational structure has not been adequately established and maintained to ensure that devices are designed and produced in accordance with 21 CFR 820.			
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Katelyn A Staub-Zamperini, Investigator Dennis R Hock, Investigator Rosanna M Goodrich, Medical Device Specialist		DATE ISSUED 8/14/2024 X _____

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Specifically, your firm's organizational structure has not assured that sterilization kits are adequately integrated into your quality management system. The responsibility for review and completion of activities associated with the (b) (4) sterilization processes has not ensured that the assembly and sterilization of kits are adequate. Observations pertaining to the (b) (4) sterilization process for the C-Section kits are examples.			
OBSERVATION 3 The design history file was not established and does not demonstrate that the design was developed following the approved design plan. Specifically, your procedure DE-01 "Design Controls" rev 00, dated July 26, 2024 does not ensure that all design history files and verification activities are completed. For example, A.) Your firm has not completed design history files for (b) (4) different FDA product codes in use at the inspected location. B.) Your firm's design procedures do not ensure that all components used in the kitting of your C-Section Pack (pack number WECS27G) have been verified acceptable for your (b) (4) sterilization process. (b) (4) out of (b) (4) components have not been reviewed.			
OBSERVATION 4 Process validation activities and results have not been adequately documented. Specifically, your firm's procedures: - PV-01 "Process Validation" revision 8, dated April 23, 2024 (and previous revisions 7 (dated 5/16/2022), 6 (dated 6/9/2021), 5 (dated 1/29/2021), 4 (dated 12/3/2019) and 3 (dated 2/20/2019)) - PR-11078 "Computerized System Validation," revision 3, dated 1/19/2022			
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FORM FDA 483 (09/08) PREVIOUS EDITION OBSOLETE INSPECTIONAL OBSERVATIONS			

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- SW-01 "Software Life Cycle Management" revision 00, dated July 01,2020 do not ensure that software validation is adequately documented. A complete set of documentation associated with the verification and/or validation of your software versions (b) (4) and (b) (4) was unable to be provided during the establishment inspection. These missing documents include signed protocols and information into testing deviations. As such the software validation could not be fully reviewed.			
*DATES OF INSPECTION 8/05/2024(Mon), 8/06/2024(Tue), 8/07/2024(Wed), 8/08/2024(Thu), 8/09/2024(Fri), 8/12/2024(Mon), 8/13/2024(Tue), 8/14/2024(Wed)			
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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Eric B. Kuebler, Operations Manager

FIRM NAME

American Contract Systems Inc

STREET ADDRESS

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Tiffin, OH 44883-9290

TYPE ESTABLISHMENT INSPECTED

Medical Device Manufacturer

Observation 1:

Observation 2:

Observation 3:

Observation 4:

**SEE REVERSE
OF THIS PAGE**

EMPLOYEE(S) SIGNATURE

Katelyn A Staub-Zamperini, Investigator
Dennis R Hock, Investigator
Rosanna M Goodrich, Medical Device
Specialist

x

DATE ISSUED

8/14/2024

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."