

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION							
DISTRICT ADDRESS AND PHONE NUMBER 404 BNA Dr., Bldg. 200, Ste. 500 Nashville, TN 37217-2597 (615) 366-7801 Fax: (615) 366-7802		DATE(S) OF INSPECTION 10/15/2024-10/16/2024 FEI NUMBER 3016690406					
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED David M Brandt, Vice President of Operations							
FIRM NAME Alon Medical Technology		STREET ADDRESS 1021 North Flowood Drive					
CITY, STATE, ZIP CODE, COUNTRY Flowood, MS 39232-9730		TYPE ESTABLISHMENT INSPECTED HCT/P Distributor					
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.							
DURING AN INSPECTION OF YOUR FIRM I OBSERVED: OBSERVATION 1 Procedures for core CGTP requirements were not reviewed and approved by a responsible person before implementation. Specifically, there is no documentation of review and approval of the firm's standard operating procedures.							
OBSERVATION 2 Procedures including release criteria for activities relating to the receipt of HCT/Ps were not followed. Specifically, the firm does not document integrity of the (b)(4) into (b)(4)							
OBSERVATION 3 Periodic quality audits of activities related to core CGTP requirements have not been performed. Specifically, 1. The firm has not performed any quality audits. 2. None of the records reviewed during the inspection contained documentation of supervisory/managerial review.							
OBSERVATION 4 Documentation of facility cleaning and sanitation activities was not maintained.							
SEE REVERSE OF THIS PAGE		<table border="0" style="width: 100%;"> <tr> <td style="width: 60%;"> EMPLOYEE(S) SIGNATURE Juanelma H Palmer, Investigator </td> <td style="width: 40%; text-align: center;"> DATE ISSUED 10/16/2024 </td> </tr> <tr> <td style="text-align: center; vertical-align: bottom;"> Juanelma H Palmer Investigator Signed By: Juanelma H. Palmer - Date Signed: 10-16-2024 12:25:54 X _____ </td> <td></td> </tr> </table>		EMPLOYEE(S) SIGNATURE Juanelma H Palmer, Investigator	DATE ISSUED 10/16/2024	Juanelma H Palmer Investigator Signed By: Juanelma H. Palmer - Date Signed: 10-16-2024 12:25:54 X _____	
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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."