

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 1201 Harbor Bay Parkway Alameda, CA 94502-7070 (510) 337-6700 Fax: (510) 337-6702	DATE(S) OF INSPECTION 9/2/2025-9/3/2025 FEI NUMBER 3017424878
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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Adam C. Sherwood, President/ Owner
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FIRM NAME Cornerstone Medical Associates, Inc.	STREET ADDRESS 205 East River Park Circle, Ste. 490
CITY, STATE, ZIP CODE, COUNTRY Fresno, CA 93720	TYPE ESTABLISHMENT INSPECTED HCT/P

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

Storage temperatures of HCT/Ps were not recorded and maintained.

Specifically,

From October 10, 2023 through January 5, 2025, your firm failed to monitor storage temperatures of (b) (4) human tissue products. During this time frame, your firm received and stored approximately (b) (4) HCT/Ps.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Amy A Johnson, Investigator	Amy A Johnson Investigator Signed By: 2001751346 Date Signed: 09-03-2025 14:46:57 X	DATE ISSUED 9/3/2025

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."