DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	3/25/2026-3/26/2026
	FEI NUMBER 3012346493

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Brendon S. Kim, Field Logistics Specialist

FIRM NAME	STREET ADDRESS
Elevate Surgical	10089 Willow Creek Rd Ste 120
CITY, STATE, ZIP CODE, COUNTRY San Diego, CA 92131-1698	TYPE ESTABLISHMENT INSPECTED HCT/P Storage & Distribution Facility

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 WE OBSERVED:

OBSERVATION 1

Equipment was not routinely inspected for adherence to maintenance schedules.

Specifically, your firm's Standard Operating Procedure for Handling HCT/Ps – Pacific Region, Ver. 1.1, Effective 8/1/2022, specifies that preventive maintenance of your Ultra-Low Freezer be performed (b) (4) (b) (4) to include a review and report for the following:

(b) (4)

During review of records, the last preventive maintenance report only documented (b) (4) the inside of the freezer and (b) (4) on August 1, 2025. The failure to conduct and document preventive maintenance activities does not ensure HCT/Ps are not adversely affected by environmental conditions.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Creighton T Tuzon, Investigator James A Banks, Investigator X Creighton T Tuzon Investigator Signed By: Creighton Tuzon -S Date Signed: 03-26-2026 13:43:11	3/26/2026

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OBSERVATION 2

Procedures for facility cleaning and sanitation were not established, maintained, defined, documented and implemented.

Specifically, your firm's Standard Operating Procedure for Handling HCT/Ps – Pacific Region, Ver. 1.1, Effective 8/1/2022, fails to specify requirements and documentation for facility cleaning and sanitation to prevent the spread of communicable diseases and cross contamination. The failure to conduct and document cleaning and sanitation compromises your ability to detect contamination trends and the spread of communicable diseases.

OBSERVATION 3

The quality program has not ensured that appropriate procedures related to core CGTP requirements were maintained, reviewed and revised.

Specifically, your firm's Standard Operating Procedure for Handling HCT/Ps – Pacific Region, Ver. 1.1, has not been updated and revised since implementation on August 1, 2022, to include the frequency of temperature data collection from your firm's Ultra-Low Freezer used to store frozen allografts such as pre-sutured tendons, (b) (4) and allograft bio-implants. For example, during a capacitor malfunction from August 18, 2025, to September 4, 2025, frozen allografts were transferred from the Ultra-Low Freezer to a (b) (4) However, temperature monitoring of the frozen allografts prior to August 18, 2025, and in the (b) (4) was not documented to evaluate conformance of frozen HCT/P storage conditions prior to distribution. The lack of documentation represents a failure to verify that critical storage parameters were met and maintained.

Also, your procedure references outdated information in part to include:

- ☐ Allograft part and serial number listed in the (b) (4)
- ☐ Changing of Temperature Charts every (b) (4)

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CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
San Diego, CA 92131-1698	HCT/P Storage & Distribution Facility

X James A Banks
Investigator
Signed By: 2004835222
Date Signed: 03-26-2026 13:43:49

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE

Creighton T Tuzon, Investigator
James A Banks, Investigator

X Creighton T Tuzon
Investigator
Signed By: Creighton Tuzon -S
Date Signed: 03-26-2026
13:43:11

DATE ISSUED
3/26/2026

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."