DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Drive, Suite 205 Lenexa, KS 66214 (913)495-5100 Fax:(913)495-5115	7/14/2025-7/15/2025
	FEI NUMBER 3011803392

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Daniel D. Calvin, Office Manager

FIRM NAME	STREET ADDRESS
Elite Orthopedics, LLC	4775 East Meyer Industrial Drive
CITY, STATE, ZIP CODE, COUNTRY Columbia, MO 65201	TYPE ESTABLISHMENT INSPECTED HCTP Establishment

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 CTGP requirements were not available to personnel in the area where operations are performed, or in a nearby area when such availability is impractical.

Specifically,

On 07/15/2025, your firm was observed using an outdated procedure, titled, *Human Tissue Product Distribution Guidance Manual - Version 1, Effective Date 2.1.16* to ensure the prevention, transmission, or spread of communicable diseases and disease agents during storage and distribution.

Below list versions of the procedure, *Human Tissue Product Distribution Guidance Manual*, with effective date created, however not made available.

- Version 2, Effective Date 01/18/2017
- Version 3, Effective Date 04/01/2018
- Version 4, Effective Date 11/06/2018
- Version 6, Effective Date 02/28/2025
- Version 7, Effective Date 06/23/2025

OBSERVATION 2

Documentation of equipment maintenance, cleaning, sanitization, and calibration was not maintained.

Specifically,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Esther A Ofori, Investigator	X Esther A Ofori Investigator Signed By: Esther A. Ofori -S Date Signed: 07-15-2025 16:33:45	7/15/2025

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Since 06/09/2023, your firm did not document pre-installation information, preventative maintenance, and control programming for the (b) (4) use to store (b) (4).

As instructed in the (b) (4) *Instructions User Manual* for the following elements,

- Unit requirements
- As needed preventative maintenance, such as battery alarm check and cleaning
- (b) (4) calibration to meet reference temperature standard

OBSERVATION 3
Storage temperatures of HCT/Ps were not recorded and maintained.

Specifically,

From (b) (4), your firm distributed (b) (4) tissue products and failed to record (b) (4) temperature of storage areas and perform a (b) (4) review of the (b) (4) *Temperature Log*.

Also, did not maintained (b) (4) calibrations records for the (b) (4) thermometer.

OBSERVATION 4
Records were not maintained concurrently with the performance of each step.

Specifically,

From 08/28/2018, your firm failed to document on the *Tissue Tracking Log*, as instructed in the procedure, titled, *Human Tissue Product Distribution Guidance, Manual, Version 1.0, Effective 2.1.16*.

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the following acceptance criteria of received tissue.

- Label verification
- Package Integrity, such as no tears, rips, or holes in packaging
- Temperature indicator, if compromised or not

OBSERVATION 5

A records management system relating to core CGTP requirements was not followed.

Specifically,

Your firm failed to follow procedure, titled, *Human Tissue Product Distribution Guidance Manual - Version 7, Effective Date 6.23.25* to document and maintain the following records relating to core Current Good Tissue Practices.

- Packing List
- Tissue Tracking Form
- Incident Report Form
- Corrective Action Request Form
- Weekly Freezer Maintenance Form
- Tissue Tracking Log

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	Esther A Ofori, Investigator	X Esther A Ofori Investigator Signed By: Esther A. Ofori -S Date Signed: 07-15-2025 16:33:45	7/15/2025

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."