DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
404 BNA Dr., Bldg. 200, Ste. 500 Nashville, TN 37217-2597 (615)366-7801 Fax:(615)366-7802	6/12/2025-6/13/2025
	FEI NUMBER 3014678321

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Jeffrey W. Dean, President/Owner

FIRM NAME	STREET ADDRESS
Performance Orthopedics Associates Inc	16 Office Park Cir Ste 9b
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Mountain Brk, AL 35223-2523	Human Tissue 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 appropriate to meet core CGTP requirements for all steps that you perform in the manufacture of HCT/Ps were not established.

Specifically,

1. There is no established procedure or records that address receipt and distribution of HCT/Ps.

2. There is no established procedure or records that addresses facility cleaning and sanitation.

3. There is no evidence of review or approval of any SOP provided.

OBSERVATION 2

The quality program has not ensured that procedures exist for information relating to core CGTP requirements, including complaints.

Specifically,

1. There is no established procedure or records addressing complaint handling.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Juanelma H Palmer, Investigator X Juanelma H Palmer Investigator Signed By: Juanelma H. Palmer - S Date Signed: 06-13-2025 12:15:21	6/13/2025

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2. There are no established procedures or records addressing investigation of HCT/P deviations relating to core CGTP requirements or adverse reactions.

OBSERVATION 3

Records were not retained for the appropriate length of time, at least 10 years after the date of a particular HCT/Ps distribution, disposition, or expiration, whichever is latest, when the date of administration is not known.

Specifically,

1. The firm did not retain any records of HCT/Ps stored and/or distributed for at least 10 years after distribution, disposition, or expiration.

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	Juanelma H Palmer, Investigator	X Juanelma H Palmer Investigator Signed By: Juanelma H. Palmer - S Date Signed: 06-13-2025 12:15:21	6/13/2025

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."