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	2/10/2025-2/19/2025* FEI NUMBER 3027320971

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Park Thomas , Chief Executive Officer

FIRM NAME	STREET ADDRESS
NuVida Medical LLC	5814 S 25th Street
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Phoenix, AZ 85040	HCT/P Warehouse/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

Storage temperatures of HCT/Ps were not maintained.

Specifically, records for your established temperature criteria of 17ºC to 28ºC to meet all manufacturers recommended storage requirements were not maintained for your storage room where you currently store allografts derived from birth tissues. Specifically, there is no record of temperatures for the following date ranges 03/31/2023 through 8/15/2023 and 9/13/2023 through 1/21/2025.

Since beginning operations of storage and distribution of HCT/Ps on 03/31/2023, your firm has distributed approximately (b) (4) units of product derived from birth tissues from your facility.

OBSERVATION 2

Incoming HCT/Ps were not accepted based on pre-established criteria designed to prevent communicable disease transmission.

Specifically, your firm has not followed your established written procedures entitled "Receiving Inspection"-SOP-OPS-002, Revision A, implemented on 03/31/2023. Since receiving and storage of HCT/P operations began in March of 2023 you have not documented your activities of evaluating incoming HCT/P's for damages or potential risks of contamination. Additionally, you have not documented whether to accept, reject, or quarantine any product that did not meet product specification.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Garrad R Poole, Investigator X Garrad R Poole Investigator Signed By: GARRAD R. POOLE - S Date Signed: 02-19-2025 07:44:31	2/19/2025

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Since beginning operations of storage and distribution of HCT/Ps on 03/31/2023, your firm has distributed approximately (b) (4) units of product derived from birth tissues from your facility.

OBSERVATION 3

Documentation for activities related to the distribution of HCT/Ps did not include activities performed and the results of each activity.

Specifically, your firm has not documented activities established in your SOP-OPS-004 entitled "Acceptance Activities" that were implemented on 03/31/2023 that were designed to make HCT/P's available for distribution. Examples of these activities not documented include:

- Performing an inspection on packaging to ensure there are no damages before distribution.
- Ensuring approved packaging and labeling were used.
- Ensuring HCT/Ps were not associated with any deviation prior to release.
- Completing FM-OPS-002 "Product Specification Form" prior to release.
- Completing "Release and Distribution Record" prior to release.
- Quality Assurance final review for disposition of the product.

Since beginning operations of storage and distribution of HCT/Ps on 03/31/2023, your firm has distributed approximately (b) (4) units of product derived from birth tissues from your facility.

***DATES OF INSPECTION**

2/10/2025(Mon), 2/11/2025(Tue), 2/12/2025(Wed), 2/14/2025(Fri), 2/19/2025(Wed)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Garrad R Poole, Investigator	X Garrad R Poole Investigator Signed By: GARRAD R. POOLE - S Date Signed: 02-19-2025 07:44:31	2/19/2025

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."