DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
250 Marquette Ave, Ste. 600 Minneapolis, MN 55401 (612)334-4100 Fax:(612)334-4134	12/4/2024-12/6/2024* FEI NUMBER 3015514993

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
William D. Methven, Co-Owner

FIRM NAME	STREET ADDRESS
Foundation Medical LLC	2060 Dodd Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Mendota Heights, MN 55120	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

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

Specifically,

a. There was no documentation of temperature monitoring during storage of human tissue products since your firm opened in May 2022 because the Wi-Fi address of the [redacted] sensor inside the tissue storage [redacted] was changed in January 2022 for an unknown reason. This change was undetected until the time of this inspection, resulting in a failure of the system to send temperature and humidity monitoring data and out of temperature alerts to you. You were unable to obtain this data from the [redacted], the associated application, or your facility HVAC [redacted] for this time period.

b. There has been no [redacted] review of human tissue storage temperature records since you started operations in May 2022, and therefore the lack of temperature and humidity monitoring that started in January 2022 was not detected by your firm.

OBSERVATION 2

Procedures appropriate to meet core CGTP requirements for all steps that you perform in the manufacture of HCT/Ps were not established, maintained, defined, documented, implemented, followed, reviewed and revised.

Specifically,

Your "RECEIVING, STORING, HANDLING AND DISTRIBUTION OF HUMAN TISSUE PRODUCTS" procedure governs all human tissue related activities at your firm.

The aforementioned procedure is inadequate to comply with human tissue regulations in that, for example:

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Kellie L Thommes, Investigator	X Kellie L Thommes Investigator Signed By: Kellie L. Thommes -S Date Signed: 12-06-2024 10:11:53	12/6/2024

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a. It does not [(b)(4)] temperature and humidity monitoring for human tissue products requiring ambient storage to ensure compliance with manufacturer temperature requirements. All of your current human tissue inventory requires storage at [(b)(4)] per the package labels.

b. It does not adequately describe, for example, [(b)(4)] of the temperature and humidity monitoring equipment ([(b)(4)]), uninterruptible application access; [(b)(4)] [(b)(4)], actions to take if data is found out of range, and documentation requirements for each step.

c. It does not adequately describe shipping packaging methods to ensure the temperature and humidity ranges as defined by the manufacturers on the product labels are maintained during shipment. For example, packing configurations, control while transported by [(b)(4)] [(b)(4)] are not defined.

***DATES OF INSPECTION**
12/04/2024(Wed), 12/06/2024(Fri)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Kellie L Thommes, Investigator X Kellie L Thommes Investigator Signed By: Kellie L. Thommes -S Date Signed: 12-06-2024 10:11:53	12/6/2024

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."