DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314	4/30/2025-5/5/2025* FEI NUMBER 3013913024

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Richard D. Mayabb, President

FIRM NAME	STREET ADDRESS
MindSight Medical LLC	3151 Halifax St Ste 160
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Dallas, TX 75247-6033	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

Acceptable temperature limits were not established for the storage of HCT/Ps at each step of the manufacturing process to inhibit the growth of infectious agents.

Specifically, your acceptable temperature limits to store room temperature (b)(4) (b)(4) HCT/Ps are not set up in accordance to manufacturer specifications and your acceptable temperature limits to store frozen (b)(4) HCT/Ps are not defined.

- The temperature probes located at the (b)(4) that monitor electronically the temperature of ambient temperature (b)(4) have a limit set between (b)(4). The manufacturer specifications of your room temperature (b)(4) HCT/Ps establish a storage temperature limit of (b)(4).
- Your Standard Operating Procedures (SOP) "Receipt, Inspection and Storage of Human Tissue Products" (Effective date: 06/17/2023) does not define what is considered acceptable temperature ranges for temperature probes located inside your (b)(4) temperature freezer that monitor ellectronically the temperature of frozen (b)(4) HCT/Ps.

Between (b)(4) your firm stored and distributed (b)(4), and (b)(4) units.

OBSERVATION 2

Corrective actions relating to core CGTP requirements.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Ramon L Gonzalez-Prieto, Investigator	X Ramon L Gonzalez-Prieto Investigator Signed By: Ramon L. Gonzalez-prieto -S Date Signed: 05-05-2025 14:19:08	5/5/2025

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Specifically, corrective actions related to temperature excursions when storing [redacted] and frozen [redacted] HCT/Ps are not defined in your Standard Operating Procedures (SOP) "Receipt, Inspection and Storage of Human Tissue Products" (Effective date: 06/17/2023).

***DATES OF INSPECTION**
4/30/2025(Wed), 5/01/2025(Thu), 5/05/2025(Mon)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Ramon L Gonzalez-Prieto, Investigator	X Ramon L Gonzalez-Prieto Investigator Signed By: Ramon L. Gonzalez-prieto -S Date Signed: 05-05-2025 14:19:08	5/5/2025

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."