DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768	2/4/2025-2/6/2025* FEI NUMBER 3019856272

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Tatiana J Jimenez, Finance and Administration Manager

FIRM NAME	STREET ADDRESS
Novutech LLC	7715 Nw 46th St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Doral, FL 33166-5460	HCT/P 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,

You failed to establish procedures and to record storage temperatures of your bone, cartilage, and tendon derived tissue products. You currently have (b) (4) total cancellous freeze-dried and cancellous cortical products in your facility that must be stored at ambient temperature. In addition, you have (b) (total demineralized bone matrix products that must be stored between (b) (4) degrees Celsius. You failed to record the temperature in the area in which you store the products and you have not established standard operating procedures. Since 2022, you have received, stored, and distributed a total of (b) (4) tissue products for export.

OBSERVATION 2

Procedures including release criteria for activities relating to the receipt, shipment and distribution of HCT/Ps were not established and documented.

Specifically,

You failed to establish and maintain standard operating procedures that define the steps your establishment must take to evaluate each incoming bone, cartilage, and tendon derived tissue products, including inspect for damage and contamination. You were not able to provide standard operating procedures that explain the steps in the determination of the acceptance, rejection, or quarantine of

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Sergio E Delgado, Investigator X Sergio E Delgado Investigator Signed By: 2003066147 Date Signed: 02-06-2025 13:11:10	2/6/2025

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incoming tissue products at your establishment. Since 2022, you have received, stored, and distributed a total of (b) (4) tissue products for export.

OBSERVATION 3

Procedures for determining if HCT/Ps that were returned to the establishment are suitable to be returned to inventory were not established, defined and documented.

Specifically,

You failed to establish and maintain standard operating procedures that define the steps your establishment must take to determine if a returned bone, cartilage, and tendon derived tissue product is suitable to be returned to inventory. You were not able to provide standard operating procedures that explain the steps in the determination of the return to inventory process. Since 2022, you have received, stored, and distributed a total of (b) (4) tissue products for export.

OBSERVATION 4

Procedures for the review, evaluation and documentation of complaints relating to core CGTP requirements were not established, defined and documented.

Specifically,

You failed to establish and maintain standard operating procedures that explain the steps taken to review, evaluate, and document complaints relating to the core current good tissue practice requirements. Since 2022, you have received, stored, and distributed a total of (b) (4) tissue products for export.

OBSERVATION 5

HCT/Ps are not tracked to facilitate the investigation of transmission of communicable disease and to take corrective actions.

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Specifically,

You failed to track the bone, cartilage, and tendon derived tissue products you have distributed and did not establish standard operating procedures. You did not establish and maintain a system of HCT/P tracking that enables the tracking of all tissue products to facilitate the investigation of actual or suspected transmission of communicable disease and take appropriate and timely corrective action. Since 2022, you have received, stored, and distributed a total of (b) (4) tissue products for export.

***DATES OF INSPECTION**
2/04/2025(Tue), 2/06/2025(Thu)

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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."