DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax:(313)393-8139	3/25/2025-4/2/2025* FEI NUMBER 3019704381

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mary Cvelbar, Sales Representative

FIRM NAME	STREET ADDRESS
Indiana Coast Medical LLC	85 E Us Highway 6
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Valparaiso, IN 46383-8947	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 WE 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,

Your firm stores and distributes HCT/Ps (human bone products) and standard operating procedures have not been established, maintained, defined, documented, and implemented for the HCT/Ps in your control since beginning HCT/P storage and distribution operations in July 2021.

Since 2021 your firm has distributed approximately (b) (4) HCT/P human bone products.

OBSERVATION 2

Incoming HCT/Ps were not evaluated for the presence and significance of microorganisms and not inspected for damage and contamination.

Specifically,

Your firm has failed to document the activities performed for verifying product acceptability, suitability, and disposition upon receipt and distribution since your firm opened and started distributing product in July 2021.

Since 2021 your firm has distributed approximately (b) (4) HCT/P human bone products.

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Gabryelle J Solverud, Investigator
David A Moore, Investigator

X Gabryelle J Solverud Investigator Signed By: Gabryelle J. Solverud - S Date Signed: 04-02-2025 14:32:39

DATE ISSUED
4/2/2025

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OBSERVATION 3

Storage areas and stock rooms were not controlled to prevent mix-ups, contamination and cross contamination of HCT/Ps, supplies and reagents and to prevent HCT/Ps from improperly being made available for distribution.

Specifically,

Your firms' products are not located in a secure area to prevent mix ups or improper release of acceptable or unacceptable product as the storage room has multiple vendors access.

Since 2021 your firm has distributed approximately (b) (4) HCT/P human bone products.

*DATES OF INSPECTION

3/25/2025(Tue), 4/01/2025(Tue), 4/02/2025(Wed)

X David A Moore
Investigator
Signed By: 2002807636
Date Signed: 04-02-2025 14:33:35

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Gabryelle J Solverud, Investigator
David A Moore, Investigator

X Gabryelle J Solverud
Investigator
Signed By: Gabryelle J. Solverud - S
Date Signed: 04-02-2025 14:32:39

DATE ISSUED
4/2/2025

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."