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	8/18/2025-8/18/2025
	FEI NUMBER 3016784205

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Pedro Yang, CEO

FIRM NAME	STREET ADDRESS
Newton Implant Systems, Inc.	440 South Melrose Drive #202
CITY, STATE, ZIP CODE, COUNTRY Vista, CA 92801	TYPE ESTABLISHMENT INSPECTED HCT/P Storage and 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

Procedures appropriate to meet core CGTP requirements for all steps that you perform in the manufacture of HCT/Ps were not followed.

Specifically, your Work Instruction "Warehouse Maintenance" SOP, WI630.01.03, effective date 2022-07-25, states that an employee is to "record the (b) (4), as well as the (b) (4) (b) (4) for the previous (b) (4)" every (b) (4) on a (b) (4). An employee additionally must verify "the cleanliness of the different (b) (4) and general (b) (4)" on the (b) (4) of each (b) (4).

The latest (b) (4) is dated to August 2024. and no other (b) (4) have been created since.
Furthermore, the latest available record was incomplete, with no verification of cleaning (b) (4) (b) (4) or general cleanliness.

Since (b) (4), your firm has shipped out (b) (4) units of tissue. As of the inspection, (b) (4) units of tissue are in storage.

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Eric Zhu, Investigator

X Eric Zhu
Investigator
Signed By: 2003017579
Date Signed: 08-18-2025
13:56:12

DATE ISSUED
8/18/2025

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."