DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
109 Holton Street Winchester, MA 01890 (781)587-7500 Fax:(781)587-7556	3/2/2026-3/5/2026*
	FEI NUMBER 3013462427

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Patrick T. O'Donnell, President & CEO

FIRM NAME	STREET ADDRESS
NanoHive Medical LLC	12 Gill St Ste 4500
CITY, STATE, ZIP CODE, COUNTRY Woburn, MA 01801-1778	TYPE ESTABLISHMENT INSPECTED Manufacturer

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.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Complaint handling records were not adequately maintained.

Specifically, your complaint files have not adequately documented as required per your *Complaint Handling* procedure, SOP-032-Rev A; Effective Date: 7/21/2017, per the following:

A. 3 of 11 complaint records reviewed did not include necessary signatures and dates indicating review.

B. 2 of 11 complaint records reviewed did not include complete documentation for regulatory reporting as required by Section 6.5.4 of SOP-032.

C. 2 of 11 complaint records reviewed did not include reference to the corrective action record that was initiated in response to the complaint or include a justification for no corrective action as required by Section 6.8 of SOP-032.

D. 4 of 11 complaint records reviewed were not processed in a timely manner.

*DATES OF INSPECTION

3/02/2026(Mon), 3/03/2026(Tue), 3/05/2026(Thu)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Nabil Nakhoul, Investigator X Nabil Nakhoul Investigator Signed By: 2001920799 Date Signed: 03-05-2026 13:15:48	3/5/2026

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Annotations to Observations

Observation 1: Not annotated

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Nabil Nakhoul, Investigator X Nabil Nakhoul Investigator Signed By: 2001920799 Date Signed: 03-05-2026 13:15:48	3/5/2026

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."