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	3/16/2026-3/19/2026
	FEI NUMBER 3042665385

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Peter R. Movilla, M.D., Clinical Investigator

FIRM NAME	STREET ADDRESS
Peter R. Movilla, MD	Mass General Brigham Newton-Wellesley Hospital, 2014 Washington Street, Main Hospital, 2nd Floor, Women's Health Center
CITY, STATE, ZIP CODE, COUNTRY Newton, MA 02462	TYPE ESTABLISHMENT INSPECTED Clinical Investigator

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:
The following observations relate to clinical trial protocol (b) (4)

OBSERVATION 1

An investigation was not conducted in accordance with the investigational plan and conditions of approval imposed by an IRB.

Specifically,

A. The protocol required a (b) (4) within (b) (4) of both the (b) (4) (b) (4) and the (b) (4)). For at least (b) (4) or (b) (4), (b) (4) results were not obtained before the procedures. On February 10, 2023, the sponsor notified Dr. Movilla, the treating sub-investigator, and the study coordinator of their concern that a (b) (4) was not completed prior to enrolling a subject in the study; however, (b) (4) were not completed as late as September 2023.

B. A research assistant with no clinical license or credentials obtained informed consent from 15 of 15

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Kent A Conforti, Investigator Agata E Libera, Investigator	X Agata E Libera Investigator Signed By: AGATA.E. LIBERA -S Date Signed: 03-19-2026 14:23:56	3/19/2026

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subjects who were consented in the study; however, MGB IRB policy is for a licensed physician or licensed doctoral-level nurse practitioner to obtain consent from subjects of more than minimal risk IDE studies.

C. The sub-investigator opened the randomization envelope for Subject (b) (6), (b) (7)(C) and did not interpret the randomization code correctly. The subject should have been randomized as a control subject but was treated with the investigational device.

D. A medical assistant not delegated to the study did not obtain (b) (4) during the Week 8 (b) (4). Independent Central Review Committee assessment of the Week 8 (b) (4) (b) (4) is the primary effectiveness endpoint.

X Kent A Conforti
Investigator
Signed By: KENT A. CONFORTI -S
Date Signed: 03-19-2026 14:24:37

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Kent A Conforti, Investigator Agata E Libera, Investigator X Agata E Libera Investigator Signed By: AGATA E. LIBERA -S Date Signed: 03-19-2026 14:23:56	3/19/2026

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."