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	3/23/2026-3/27/2026 FEI NUMBER 3042755766

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Benjamin D. Elder, MD, PhD, Clinical Investigator

FIRM NAME	STREET ADDRESS
Benjamin D. Elder, MD, PhD	200 First Street SW, Mayo Clinic (Minnesota)
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Rochester, MN 55905	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 I OBSERVED:
For Study Protocol (b) (4)

OBSERVATION 1

An investigation was not conducted according to the investigational plan.

Specifically,

A. Per Protocol section 12.4 and 12.5, (b) (4) physical exams are required as part of the post-(b) (4) evaluation. The (b) (4) physical exams were not completed for 2 of 10 enrolled subjects as noted below:

Subject ID	Visit(s)
(b) (6), (b) (7)(C)	Visit 4 ((b) (4)
	Visit 4 ((b) (4)
	Visit 5 ((b) (4))

OBSERVATION 2

Records of use of a device that relate to the dates of receipt and batch number or code mark of the device are not all accurate and complete.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Stephen O Agyemang, Investigator X Stephen O Agyemang Investigator Signed By: STEPHEN O. AGYEMANG -S Date Signed: 03-27-2026 13:37:36	3/27/2026

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Specifically, for subject (b) (6), (b) (7)(C) neither the device accountability records, nor the shipping records document the lot number of the investigational device to which the subject was assigned and randomized. The subject was assigned to lot number (b) (4) which is not documented in either record.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Stephen O Agyemang, Investigator	X Stephen O Agyemang Investigator Signed By: STEPHEN O. AGYEMANG -S Date Signed: 03-27-2026 13:37:36	3/27/2026

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."