DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
11155 Dolfield Boulevard, Suite 117 Owings Mills, MD 21117 (410)779-5455 Fax:(410)779-5707	2/24/2025-2/28/2025
	FEI NUMBER 3033061128

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Jonathan E. Isaacs, MD, Clinical Investigator

FIRM NAME	STREET ADDRESS
Jonathan E. Issacs, M.D.	1200 E Broad St, VCU Health System Department of Orthopaedic Surgery
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Richmond, VA 23298-5025	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:
The observations listed below were observed during the review of the studies entitled:

A Multicenter, Prospective, Randomized, Subject and Evaluator Blinded Comparative Study of Nerve Cuffs and Avance® Nerve Graft Evaluating Recovery Outcomes for the Repair of Nerve Discontinuities (RECON)

OBSERVATION 1

Failure to permit an authorized officer or employee of FDA to have access to and verify records or reports.

Specifically,

The temperature logs documentation for the investigational product for the entire duration of the clinical trial first subject enrolled on 6/17/2015 and the date of the last subject's last visit on 12/15/2020 was not provided.

OBSERVATION 2

Failure to report serious adverse events promptly to the sponsor.

Specifically,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Lucilla Facchin, Investigator X Lucilla Facchin Investigator Signed By: LUCILLA FACCHIN -S Date Signed: 02-28-2025 15:15:22	2/28/2025

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
11155 Dolfield Boulevard, Suite 117 Owings Mills, MD 21117 (410)779-5455 Fax:(410)779-5707	2/24/2025-2/28/2025
	FEI NUMBER 3033061128

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Jonathan E. Isaacs, MD, Clinical Investigator

FIRM NAME	STREET ADDRESS
Jonathan E. Issacs, M.D.	1200 E Broad St, VCU Health System Department of Orthopaedic Surgery
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Richmond, VA 23298-5025	Clinical Investigator

On 3/18/2019, Subject [redacted] was hospitalized due to an [redacted (b)(6) (b)(7)(C)] and had [redacted (b)(6) (b)(7)(C)]. This was the [redacted] that received the investigational product. The event was reported as a serious adverse event on 4/3/2019, [redacted (b)(4)] the occurrence. The protocol specify that a serious adverse event needs to be reported to the sponsor within [redacted (b)(4)] of its occurrence. A sub-investigator performed the [redacted].

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Lucilla Facchin, Investigator X Lucilla Facchin Investigator Signed By: LUCILLA FACCHIN -S Date Signed: 02-28-2025 15:25:22	2/28/2025

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."