DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 Main Street, Ste 4-930 Cincinnati, OH 45202 (513)322-0700 Fax:(513)679-2772	12/17/2025-12/31/2025* FEI NUMBER 3040335429

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Jae S. Cho, M.D, Clinical Investigator

FIRM NAME	STREET ADDRESS
Jae S. Cho, M.D	University Hospitals Cleveland Medical Center , 11100 Euclid Avenue
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Cleveland, OH 44106	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 following observations pertain to the Clinical Investigator's conduct of TRIOMPHE Clinical Study Protocol CIP009.

OBSERVATION 1

An investigation was not conducted according to the signed agreement.

Specifically, Protocol version 1.8 dated 26 MAR 2021, Table 6 Investigator Reporting Responsibilities, requires reporting of serious adverse events (SAE), be reported to the sponsor no later than (b) (4) after the investigator is first aware of the event.

- ☐ Subject (b) (6), (b) (7)(C) experienced an SAE on (b) (6), (b) (7)(C) The site became aware of the SAE on 4/22/25. The SAE was not entered into the electronic database until 10/1/25.
- ☐ Subject (b) (6), (b) (7)(C) experienced an SAE on (b) (6), (b) (7)(C) The site became aware of the SAE on 4/22/25. The SAE was not entered into the electronic database until 10/1/25.
- ☐ Subject (b) (6), (b) (7)(C) experienced an SAE on (b) (6), (b) (7)(C) The site became aware of the SAE on 6/28/23. The SAE was not entered into the electronic database until 8/1/23.

OBSERVATION 2

Informed consent was not properly documented in that the written informed consent used in the study was not approved by the IRB.

Specifically, while reviewing the consent document with subjects, the study coordinator altered the NEXUS Aortic Arch Stent Graft System Procedure section as follows:

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Brittany M Kershaw, Investigator

X Brittany M Kershaw
Investigator
Signed By: Brittany M. Kershaw - S
Date Signed: 12-31-2025 12:15:35

DATE ISSUED
12/31/2025

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☐For Subjects (b) (6), (b) (7)(C) the phrase "mild sedation and local" was crossed out and replaced with "general" in the section discussing the anesthesia given during the procedure.
☐For Subjects (b) (6), (b) (7)(C) the word (b) (4) was crossed out and replaced with (b) (4) in the section discussing redirection of blood flow via bypass.

***DATES OF INSPECTION**
12/17/2025(Wed), 12/18/2025(Thu), 12/19/2025(Fri), 12/22/2025(Mon), 12/30/2025(Tue), 12/31/2025(Wed)

SEE REVERSE OF THIS PAGE

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Investigator
Signed By: Brittany M. Kershaw - S
Date Signed: 12-31-2025 12:15:35

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12/31/2025

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."