DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973) 331-4900	5/27/2026-6/25/2026* FEI NUMBER 1000121696

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Monte Nelson, Director of Quality Affairs

FIRM NAME	STREET ADDRESS
LeMaitre Vascular, Inc.	206 N Center Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
North Brunswick, NJ 08902-4246	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 WE OBSERVED:

OBSERVATION 1

Production and service provision was not adequately planned, carried out, monitored, and controlled to ensure that product conforms to specification.

Specifically,

A. There was no rationale for the (b) (4) sample bioburden action limit point, which is set at the limit of detection in SOP 142, Routine (b) (4) Bioburden Testing, Section 6.11.1.

B. In SOP 142, Routine (b) (4) Bioburden Testing, Section 6.11, Action Level, the action level does not require any action to be taken to control the non-conforming product other than trending when the action level is exceeded and a review of any anomalies from previous lots and an investigation if other anomalies are detected in other lots.

OBSERVATION 2

Arrangements were not adequately planned and documented for the control of contaminated or potentially contaminated product in order to prevent contamination of the work environment, personnel, or product.

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Specifically, sampling of (b) (4) for the (b) (4) system used to produce (b) (4) for production of the (b) (4) includes (b) (4) of the (b) (4) system prior to sampling, which is not consistent with production. For example, SOP 103, Sampling of the (b) (4) System, Rev, Q, Section 6.13.2, requires (b) (4) when sampling the (b) (4) system. PS001, Processing of the (b) (4) , Section 6.1.4, requires cleaning and (b) (4) of the (b) (4) system workstation (b) (4) at the (b) (4) of each day. No additional (b) (4) is required by the procedure when using (b) (4) for production.

OBSERVATION 3

Nonconforming product was not evaluated to determine the need for an investigation and notification of any external party responsible for the nonconformity.

Specifically, NCMR-000746, opened 8/20/2025 to address (b) (4) samples exceeding the action limit of (b) (4), does not include a review of all previous lots from that (b) (4) for any anomalies as required by SOP-142, Routine (b) (4) Bioburden Testing, which states in Section 6.11.3, Action Level, "If a sample exceeds the action level, all previous results from that (b) (4) will be reviewed for any anomalies that may have contributed to the results. This includes a review of the receiving records and if the alert/action level has been consistently exceeded."

OBSERVATION 4

Procedures were not adequately documented for preserving the conformity of product to requirements during processing, storage, handling, and distribution.

Specifically, your firm has not established adequate scientific justification for the storage and transportation temperature specification of (b) (4) and the maximum storage duration of (b) (4) for (b) (4) ('(b) (4) Material Specification", document # RM 001, Revision Q) used in the manufacture of the (b) (4). Your firm provided a memorandum dated June 8, 2026, referencing peer-reviewed literature and industry standards. The cited studies were conducted using various

(b) (4) types, none of which included (b) (4), at temperatures up to (b) (4) in preservative or physiological solutions under controlled laboratory conditions, and do not address bacterial bioburden growth at any temperature.

The industry standards cited apply to (b) (4) processed under controlled tissue bank conditions with antimicrobial treatment. Your firm's memorandum acknowledges that regulatory and pharmacopeial references generally define refrigerated storage as 2°C to 8°C, yet your firm's specification permits temperatures up to (b) (4), with measurement uncertainty and transport fluctuations offered as justification for exceeding the standard range. Your firm has not provided prospective validation data, time-temperature stability studies, or microbial growth kinetics data demonstrating that the (b) (4) specification for up to (b) (4) adequately controls bacterial bioburden in (b) (4). Your firm's (b) (4) Receipt Log documents approximately (b) (4) incoming (b) (4) shipments from (b) (4) suppliers from May 1, 2025, through May 21, 2026. Review of your firm's nonconformance log for the same period identified 230 temperature excursion nonconformances.

OBSERVATION 5

Corrective action procedures defining the requirements for verifying that the corrective action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the medical device have not been documented.

Specifically,

A. CAPA-00097 was opened 5/16/2025 to address multiple manufacturing workstations with pre-sterile excursions of high bioburden levels exceeding the action level. Changes were made to the PS 001, Processing the (b) (4) procedure. Section 6.11.3.10.11 of the procedure states if the (b) (4) were placed into the (b) (4) culture tube, the manufacturing technician may begin initial cleaning. Section 6.11.3.10.12 states after completing the initial cleaning (b) (4) for approximately (b) (4) and if the (b) (4) were placed (b) (4) into the (b) (4) culture tubes, after (b) (4) has been completed return the (b) (4) (b) (4) holding the cleaned rod back into the (b) (4) culture tube. The CAPA was verified as effective. The

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CAPA was closed on 5/22/2026.

CAPA-0108 was opened 5/18/2026 to address high presterile bioburden excursions (b) (4)) in (b) (4) production lots sampled in April of 2026. (b) (4) of the production lots (b) (4) were the same lots used to verify the effectiveness of CAPA- 00097. The investigation and Root Cause Analysis states the revised workflow (which was changed as part of CAPA-00097) resulted in direct exposure of the internal surfaces of the pre-sterile packaging components to (b) (4) in-process (b) (4) prior to completion of the established (b) (4) step intended to reduce residual bioburden.

B. CAPA-00096, opened May 8, 2025, was opened to address a trend of temperature data logger nonconformances for incoming (b) (4) shipments and was closed on May 6, 2026, without adequate verification of effectiveness. The effectiveness verification plan specified a (b) (4) monitoring period with an acceptance criterion of at least (b) (4) reduction in temperature and data logger related nonconformances compared to the October 2024 through February 2025 baseline. The actual monitoring period was approximately seven weeks — March 7, 2026, through April 28, 2026 — with no documented justification for shortening the predefined duration. Your firm also acknowledged during the inspection that seasonal variation was not considered in the CAPA design or verification of effectiveness planning.

Three domestic temperature excursion NCMRs were opened within approximately one week of CAPA-00096 closure, on May 12, 13, and 14, 2026, all involving the same (b) (4) . Your firm provided a memorandum dated June 8, 2026, extending the verification of effectiveness analysis through June 5, 2026, documenting 12 NCMRs during the March 7 through June 5, 2026, period and reporting an 83% reduction — declining from the 87% reduction observed at the time of CAPA closure on May 6, 2026. Review of your firm's NCMR log from May 2025 through May 2026 demonstrates that July and August 2025 account for approximately 47 of 230 temperature excursion NCMRs (20.4% of all temperature excursion nonconformances), while the March 7 through April 28, 2026, monitoring period accounts for approximately 13 of 230 (5.7% of temperature excursion nonconformances). The verification of effectiveness monitoring period concluded prior to July and August 2026.

OBSERVATION 6

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Preventive action procedures describing the requirements for planning and documenting action needed and implementing such action have not been adequately documented.

Specifically, corrective and preventive actions have not been fully implemented prior to closing corrective and preventive actions. For example, CAPA-00091, opened to address observation 4 from the previous inspection concerning lack of statistically significant bioburden data for raw materials and components used in the (b) (4) The actions included begin testing raw materials and components. The root cause was that SOP 100 did not require testing of raw materials and components. The corrective action was to create procedures for sampling, testing, and analyzing raw materials and (b) (4) bioburden.

The Verification of Effectiveness referenced the Material Bioburden Determination Worksheet (FRM-141-01), approved as record RCD-141-01-001, Rev. A. RCD-141-001 Rev. A, Section 4.2 states Action and Alert Levels for (b) (4) were determined by the 2023 Sterilization Annual Review and will be re-evaluated in the 2024 Sterilization (b) (4) Review (to be completed in 2025). The CAPA was closed by the actions limits still had not been determined.

OBSERVATION 7

Design and development inputs related to product requirements do not adequately include requirements essential for design and development of the product and processes.

Specifically, the Design Faliure Modes and Effects Analysis (DFMEA), Reference number D.009, states (b) (4) must maintain adequate material and structural integrity for (b) (4) into the (b) (4) It references VAL-7198-2023 as the verification of risk control effectiveness. The VAL-7198-2023 (b) (4) Product Testing per ISO 7198:2016 states in Section 1, Purpose, the objective of the document is to assess the design of the (b) (4) in accordance with (b) (4) , Section (b) (4) (b) (4) . (b) (4) (b) (4) , Section (b) (4), includes requirement such as the ability to (b) (4) and the ability to (b) (4) . There was no determination of whether or not the (b) (4) would maintain its (b) (4) integrity if (b) (4) where an (b) (4) is present. Complaint number 190 was received concerning (b) (4) of the (b) (4) in a patient with an (b) (4) .

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OBSERVATION 8

Information gathered in the feedback process does not serve as potential input into risk management for monitoring and maintaining product requirements as well as the product realization or improvement processes.

Specifically, the Process Failure Modes and Effects Analysis (PFMEA), Design Failure Modes and Effects Analysis (DFMEA), and User Failure Modes and Effects Analysis (UFMEA) for the (b) (4) it did not include the hazard of (b) (4) resulting from (b) (4) . Complaint-00190, created 10/6/2025 was received concerning a patient with a (b) (4) resulting in (b) (4) and (b) (4) of the (b) (4). The Complaint Analysis of Data did not identify this as a new risk/hazard.

***DATES OF INSPECTION**

5/27/2026(Wed), 5/28/2026(Thu), 6/01/2026(Mon), 6/02/2026(Tue), 6/03/2026(Wed), 6/04/2026(Thu), 6/08/2026(Mon), 6/09/2026(Tue), 6/10/2026(Wed), 6/11/2026(Thu), 6/16/2026(Tue), 6/25/2026(Thu)

X Matthew W Kyle
Investigator
Signed By: Matthew W. Kyle -S
Date Signed: 06-25-2026 10:09:42

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Annotations to Observations

Observation 1: Not annotated

Observation 2: Not annotated

Observation 3: Not annotated

Observation 4: Not annotated

Observation 5: Not annotated

Observation 6: Not annotated

Observation 7: Not annotated

Observation 8: Not annotated

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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."