DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Harbor Bay Parkway Alameda, CA 94502-7070 (510)337-6700 Fax:(510)337-6702	3/9/2026-3/11/2026 FEI NUMBER 3004142795

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Monica A. Barrett, Director of Regulatory and Quality

FIRM NAME	STREET ADDRESS
Mercator Medsystems, Inc.	520 McCormick Street
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
San Leandro, CA 94577	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 I OBSERVED:

OBSERVATION 1

Justification for not investigating a complaint(s) was not documented.

Procedures for complaint handling have not been adequately implemented. Specifically, complaints are not always investigated, and when no investigation is conducted, a rationale is not documented.

Specifically,

A review of your firm's complaint files revealed that the investigation requirements established in your procedure, SOP0025 *Product Complaint Reports,* Rev 6, Effective Date: 3/5/2026, Section 5.2, is not adequately implemented.

For example, complaint CC-071323-01, date 7/17/2023, concerning a Leapfrog Micro-Infusion Device (Lot: [redacted], documented an alleged device malfunction that occurred on 07/13/2023. The complaint details state, "On deflation, blood was noticed in the in deflator... It was determined that a pinhole leak may have let blood in on deflation but sealed upon inflation of the device." This is an allegation of a deficiency related to device performance and reliability. A review of the completed file for complaint CC-071323-01, which was closed on 07/20/2023, showed the following: No failure investigation was

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Kevin T Le, Inspector	X Kevin T Le Inspector Signed By: 2003985283 Date Signed: 03-11-2026 14:06:23	3/11/2026

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conducted; the "Product Complaint Close-Out Checklist" (FRM0041) for this complaint indicates the "Product Complaint Failure Investigation Form" (FRM0040) was considered "N/A" (Not Applicable); and the complaint file contained no documented rationale or justification explaining the decision not to conduct an investigation into the reported malfunction.

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FIRM NAME Mercator Medsystems, Inc.	STREET ADDRESS 520 McCormick Street
CITY, STATE, ZIP CODE, COUNTRY San Leandro, CA 94577	TYPE ESTABLISHMENT INSPECTED Manufacturer

Annotations to Observations

Observation 1: Promised to correct

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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."