DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
109 Holton Street Winchester, MA 01890 (781)587-7500 Fax:(781)587-7556	3/18/2026-3/20/2026
	FEI NUMBER 3013660213

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Windi A. Hary, Windi A. Hary, Chief Quality and Regulatory Officer

FIRM NAME	STREET ADDRESS
Elucid Bioimaging Inc.	399 Boylston Street, Suite 400
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Boston, MA 02116-3932	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

Procedures for timely complaint handling have not been adequately documented.

Specifically,

A. Your firm's procedure "822-SOP-001 Complaint Handling Procedure", version 6.0, effective February 23, 2026 does not adequately define the process for determining when complaints require corrective and preventive action.

Section 6.2.3 addresses corrective action for individual complaints (analyst error, defects, rework) but does not define criteria for when complaints trigger evaluation for CAPA per the firm's Corrective and Preventative Action Process procedure 852-SOP-001 v4.0. The procedure does not reference 852-SOP-001 or establish a process to evaluate complaints against CAPA determination criteria.

B. Your firm did not conduct the initial Medical Device Reporting determination within the required timeframe required by your procedure, for one out of 5 complaints reviewed.

Section 6.2.1 of the complaint procedure states, "This initial reporting determination will take place within (b) (4) days of the aware date for applicable regulatory regions." Complaint CN-

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	James P Finn, Investigator X James P Finn Investigator Signed By: 2001623919 Date Signed: 03-20-2026 12:44:51	3/20/2026

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000013 had an aware date of (b) (4), but was not opened until August 21, 2025, (b) (4) days after the aware date. The Medical Device Reporting determination was completed on August 21, 2025, exceeding the (b) (4) day requirement by (b) (4) days.

C. Specifically, your firm's Complaint Procedure does not include provisions for capturing and documenting any unique device identifier (UDI) or Universal Product Code (UPC) in the complaint investigation record. Five out of five complaint files reviewed do not document any UDI. Complaint files: CN-000004, CN-000007, CN-000013, CN-000014 and CN-000017 do not document any UID.

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Annotations to Observations

Observation 1: 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."