DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	7/1/2026-7/6/2026* FEI NUMBER 3013634985

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Fei Gao (nmi), President

FIRM NAME	STREET ADDRESS
GUIDEMIA TECHNOLOGIES LLC	6532 University Way
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Buena Park, CA 90620-4600	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.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

Records of corrective actions, including the results of any investigations and actions taken, were not adequately maintained.

Specifically,

Your firm, GuideMia Technologies LLC, is a manufacturer of (b) (4) that is used for (b) (4) applications.

Your firm's 510(k) submission for your (b) (4) System, also known as (b) (4) states that its indications for use are "The (b) (4) system is intended as (b) (4) "

Your firm's 510(k) submission for your (b) (4) System states "(b) (4) system is intended for use as (b) (4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Jordan I Abel, Investigator Joseph C Onyeike, Investigator X Jordan I Abel Investigator Signed By: 2004376737 Date Signed: 07-06-2026 13:38:47	7/6/2026

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(b) (4)

I reviewed CAPA-2023-02, CAPA-2024-01, CAPA-2025-03, and CAPA-2026-02. Each of these CAPAs were one page records. The root cause analysis section does not include the steps taken to determine the root cause, rather it states what the root cause was determined to be. For example for CAPA-2026-02, which is marked as closed, the root cause analysis section only states "RC convention introduced open items for the first time; per-item owner field not yet in template." The steps taken to reach this conclusion were not documented.

Additionally, your firm's procedure, GP-83-002, GuideMia CAPA Procedure, V1.1, 1/21/14, does not mention how to verify the effectiveness of a corrective action and does not discuss effectiveness monitoring periods. All four CAPA records that I reviewed do not have a section for verification of effectiveness.

OBSERVATION 2
Complaint handling records were not adequately maintained.

Specifically,

Your firm stated that your procedure for complaint handling is TCF-13, Rev 5.0, 5/5/21, PMS & Vigilance System. Your firm also has GP-83-003, V1.0, 12/18/13, Guidemia Medical Device Report (MDR) Procedure.

I requested a record of all of complaints from 2023 to present and was provided with your GuideMia Customer Requests and Complaints Log. When I requested specific complaint records from your list of complaints, your firm's management stated that you do not have individual files for complaints. You stated that the only information you have regarding specific complaints are the GuideMia Customer

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Requests and Complaints Log and your emails with customers.

GP-83-002,V1.1, 1/21/14, Guidemia CAPA Procedure, states "When a customer complaint is received, it is evaluated by QA first. If applicable, an MDR or/and IR incident report (IR) will be documented for the complaint. Regardless the complaint is an MDR/IR reportable event or not, a Problem Report (PR) is filed for development purposes." However, your GuideMia Customer Requests and Complaints Log does not show an evaluation of whether the complaint is MDR reportable or not. This log also does not contain an evaluation of whether a complaint requires correction or corrective action.

OBSERVATION 3

Training has not been adequately provided, or other actions needed taken, to achieve or maintain the necessary personnel competence.

Specifically,

Your firm's procedure GP-62-001, GuideMia Employee Training Procedure, V.1.1, 12/15/15, states "Company quality system training is to train employees the basics of company quality management system at the higher level. The subjects will include Quality Manual, QMS procedures (according to employees' responsibility), forms, etc." The latest revision of your firm's quality manual is GP-41-001, V1.6, 1/15/18, GuideMia Quality Manual. However, your firm has no record of your personnel training to any revisions of your quality manual. Additionally, management personnel stated that you do not have any internal training for the last three years because you are familiar with software and quality management systems.

OBSERVATION 4

The correct unique device identifier (UDI) information regarding device identifier portion of the UDI assigned to the version or model was not provided to the FDA via the Global Unique Device Identification Database (GUDID).

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Specifically,

None of your firm's devices are registered on GUDID.

***DATES OF INSPECTION**
7/01/2026(Wed), 7/02/2026(Thu), 7/06/2026(Mon)

X Joseph C Onyeike
Investigator
Signed By: JOSEPH C. ONYEIKE -S
Date Signed: 07-06-2026 13:41:48

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Annotations to Observations

Observation 1: Promised to correct

Observation 2: Promised to correct

Observation 3: Promised to correct

Observation 4: Annotation Intentionally Left Blank

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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."