DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax:(313)393-8139	5/26/2026-6/2/2026* FEI NUMBER 3016261131

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Tracy M. Momany, President and CEO

FIRM NAME	STREET ADDRESS
Guardian Medical USA Inc.	11360 S Airfield Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Swanton, OH 43558-7900	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 transfer of design and development outputs to manufacturing were not documented.

Specifically,

Your firm has not established documented procedures for design and development or for the transfer of design and development outputs to manufacturing. No design controls are in place to govern design and development activities, and no design transfer procedure exists to verify that design outputs are suitable for manufacturing prior to becoming final production specifications.

OBSERVATION 2

Validation of processes for production and service provision did not adequately demonstrate the ability of the processes to achieve planned results consistently.

Specifically,

Your firm failed to follow its own procedure, Process Validation procedure SOP-021 (Rev. K, Eff. 08 Jul 2025), as validation documentation is incomplete and inadequately controlled across multiple processes.

AMENDMENT 1

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	Felicia E Armbrustmacher, Investigator X Felicia E Armbrustmacher Investigator Signed By: FELICIA E. ARMBRUSTMACHER -S Date Signed: 06-02-2026 14:21:33	6/2/2026

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☐PGM18006 / RGM18006 – Equipment (b) (4) Operational Qualification (Cleaning Validation): The Operational Qualification (OQ) for equipment (b) (4) recorded out-of-specification temperature values that were neither addressed nor documented as a deviation, including the (b) (4) stage, where the (b) (4) sensor recorded a temperature of 70.3°F (21.3°C) and the (b) (4)) recorded 75.0°F (23.9°C) — both falling "~~below~~ **within**" the expected operational temperature range — while the temperature at time of run reached 85.2°F (29.6°C), indicating a discrepancy across measurement points that was not formally investigated or resolved.

☐PGM19028 / RGM19028 – Cleaning Verification Study, (b) (4) : Raw test data documenting how individual parts were produced is absent; only summary data is present. Your firm could not provide raw data records to support validation conclusions.

☐PGM18024 / RGM18024 – Cleaning of (b) (4) Validation Study: The validation study omits documented visual test results evaluated against acceptance criteria. This incomplete validation record was distributed to customers as evidence of your firm's capability to clean Class II products.

OBSERVATION 3

A risk-based approach to the control of the appropriate processes needed for the quality management system has not been adequately applied.

Specifically,

Your firm has not established a uniform risk-based approach across QMS processes. The CAPA Procedure (SOP-027, Rev. I, Appendix I) determines risk impact via a (b) (4) matrix yielding (b) (4) levels. The Supplier Evaluation Procedure (SOP-017, Rev. K, Table 5)

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assigns SCAR risk using separate criteria. The Risk Management Procedure (SOP-036, Rev. G) governs risk through PFMEA-based (b) (4) scoring per SOP-038, Rev. H. No procedure defines how these methodologies are reconciled across the QMS.

OBSERVATION 4

Procedures to define the controls and related responsibilities and authorities for the identification, documentation, segregation, evaluation, and disposition of nonconforming product were not adequately documented.

Specifically,

Part A.

Your firm has no documented process for identifying and tracking the duration of quality holds - items which may include (b) (4) class II devices, that are physically placed on a shelf with no mechanism to establish timing or oversight.

Part B.

To date, your Nonconforming Material procedure SOP – 026 (Rev. K, Effective 20 Mar 2025) does not define a timeframe for transferring quality holds to nonconformance reports or specify whether multiple discrete quality hold events may be consolidated into a single NCR. For example, NCR-0296 combined four separate nonconformance events into one record, understating true nonconformance frequency. This also occurred for NCR-0209, NCR-0238, and NCR-0304.

OBSERVATION 5

Criteria for the evaluation of suppliers were not adequately established.

Specifically,

Part A.

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Your firm is not following your Supplier Controls procedure SOP-017 (Rev. K, Effective 20 Mar 2025) which requires a SCAR issuance when supplier error is identified, yet no SCARs were generated for nonconformances and complaints with confirmed supplier root causes, and no justification for non-issuance was documented.

Part B.

Your firm's Supplier Controls procedure SOP-017 (Rev. K, Effective 20 Mar 2025) requires that when a supplier could qualify at a lower criticality level but supplies a higher-risk product or service, the highest level of criticality must govern the supplier's classification. Your firm did not apply this rule to two suppliers:

- Supplier (b) (4) was not escalated to a Level 1 supplier status despite a supporting memo (Dated 25 May 2024) stating it was a high criticality supplier.
- Supplier (b) (4) a level 2 supplier, supplies cleaning equipment for Class II (b) (4) — a service meeting the procedure's definition of Level I risk, where unmet specifications may cause unreasonable risk or significant degradation of device performance.

OBSERVATION 6

Corrective action procedures defining the requirements for reviewing nonconformities and evaluating the need for action to ensure that nonconformities do not recur have not been adequately documented.

Specifically,

Part A.

Across four NCRs (NCR-0209, NCR-0238, NCR-0296, NCR-0304) spanning July 2022 through

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January 2024, foreign debris, fuzz, and particulate were identified in assemblies of Class II (b) (4) devices across (b) (4) affected lots during labeling and (b) (4) operations. Your firm has had at least two complaints related to foreign particulate, C-0052 and C-0031. The failure mode of foreign debris and particulate ingress during labeling and (b) (4) was not defined in the Process Failure Mode and Effects Analysis (pFMEA); no structured risk assessment was performed for this failure mode, and no Corrective Action and Preventive Action (CAPA) was initiated. To date, your firm currently has no defined threshold for CAPA initiation in your procedure Corrective and Preventive Action SOP – 27 (Rev. I, Effective 17 Jun 2025).

Part B.

Your firm's SOP-027 (Rev. H, Effective 09 Mar 2023; Rev. I, Effective 17 Jun 2025) does not require that corrective actions taken in response to nonconformances — including work instruction updates and preventive maintenance changes — be initiated through, or linked to, the Corrective Action (CA) system. For Nonconformance Report NCR - 0351 (initiated 01 Jul 2024) — water of unknown origin identified in the cleanroom used to clean and package Class II (b) (4) devices — your firm implemented a work instruction update and a preventive maintenance change outside the Corrective Action system, with no effectiveness evaluation or adverse product impact assessment completed.

***DATES OF INSPECTION**
5/26/2026(Tue), 5/27/2026(Wed), 5/28/2026(Thu), 5/29/2026(Fri), 6/01/2026(Mon), 6/02/2026(Tue)

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Annotations to Observations

Observation 1: Promised to correct

Observation 2: Promised to correct

Observation 3: Promised to correct

Observation 4: Promised to correct

Observation 5: Promised to correct

Observation 6: Promised to correct

AMENDMENT 1

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DATE ISSUED
6/2/2026

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."