DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 Main Street, Ste 4-930 Cincinnati, OH 45202 (513)322-0700 Fax:(513)679-2772	2/4/2026-2/17/2026* FEI NUMBER 1000160007

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Edward M. Carter, President/COO

FIRM NAME	STREET ADDRESS
Mirac LLC	2153 Winners Cir
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Dayton, OH 45404-1150	Medical Device 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 to define the controls and related responsibilities and authorities for the identification, documentation, segregation, evaluation, and disposition of nonconforming product were not documented.

Specifically, your procedure SOP-0006, "Control of Nonconforming Material" rev B, dated 11/11/2025 (as well as previous revision A, dated 11/1/2023) does not ensure that nonconforming products and the associated rework are identified and controlled.

~~A) According to your RMA database, a total of (b) (4) units were returned to your firm via an RMA. This is out of a total of (b) (4) units that we have shipped to your customer.~~

A) A) Nonconforming devices are sent to your customer for troubleshooting but are included on your Certification of Compliance (CoC) which states that the products delivered are conforming to "customer supplied design files and specifications and have been tested to these specifications prior to packaging." For example, the CoC for parts returned to your customer (b) (4) after RMA 3831 state that there are (b) (4) conforming units. Your router designates from 6/20/2025, that 1 out of the (b) (4) units had a (b) (4) issue and (b) had a glue issue. **According to your RMA database, a total of (b) (4) units**

AMENDMENT 1

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were returned to your firm via an RMA. This is out of a total of (b) (4) units that we have shipped to your customer.

B)

~~C)~~ **B)** Your firm does not maintain copies of final inspection test reports associated with the (b) (4) product line. These records were unavailable to verify the final specification conformance for all serial numbers.

~~D)~~ **C)** Rework activities are not recorded in a way to know what is completed on each serial number. For example, RMA 3831, dated 4/29/25, is associated with (b) (4) serial numbers that were found to be nonconforming. These units were analyzed by your customer and shipped back for correction and/or testing. Rework was completed on 5/19/2025 and again on 6/16/2025 but your rework activities are not documented in a way to know what was corrected on each serial number.

~~E)~~ **D)** Rework activities are being conducted by your customer without documentation of what was corrected being documented within your records or how this is to be controlled. For example, for RMA 3831, several documents were provided by your customer providing analysis. Several units mention a correction to nonconforming issues. This includes the (b) (4) device with the serial number (b) (4) which states that they replaced the (b) (4) and that your firm only needed to test it.

OBSERVATION 2

Processes for production and service provision where the resulting output cannot be, or is not, verified by subsequent monitoring or measurement were not adequately validated.

Specifically, procedure SOP-0019 “Validation of Processes for Production” rev B, dated 1/30/2024 and procedure P-7.5.6 “Validation of Processes for Production” rev A, dated

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12/2/2021 does not ensure that processes are adequately validated. For example,

The Validation Protocol and the Protocol Completion Report, numbered VP-001, dated 11/18/23 for the (b) (4)), with the serial number (b) (4) , was not adequate. This validation did not ensure that the validation of the (b) (4) had appropriate acceptance criteria and was concerned about "reliability'. You did not show that the (b) (4) had repeatability and process capability.

Furthermore, your firm has failed to ensure that all manufacturing process used in the manufacturing of the Class 2 devices (b) (4) and (b) (4) and require validation have been validated. Examples of these processes include:

- (b) (4) process
- The (b) (4) process
- The (b) (4) process
- Visual inspection
- Final test inspection.

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, procedure P-8.5-3 "Risk Management and Preventative Action," rev G, dated 11/29/21 is not adequate to ensure that you are able to define risk within your quality system. For example, the procedure does not define your requirements for assigning "severity", "likelihood of occurrence" and "detectability" which is used for assigning "risk assessment and the need for action".

Furthermore, your firm has not considered and documented the risk for your production processes used in the manufacturing of the 2 Class 2 devices manufactured at your firm

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((b) (4) and (b) (4)).

OBSERVATION 4

Top management did not ensure that responsibilities and authorities are adequately defined, documented, and communicated within the organization.

Specifically, your management has not documented how responsibility is defined within the organization. This includes ensuring that procedures, processes, and staff are controlled including at your corporate location. For example,

A) Your management does not define which locations are responsible for which parts of all production process of the (b) (4) " and (b) (4) class 2 devices.

B) Your management has not defined which procedures from corporate are to be used at the manufacturing location.

OBSERVATION 5

Procedures to describe the responsibilities and requirements for planning and conducting internal audits and recording and reporting audit results were not adequately documented.

Specifically, procedure SOP-0041, "Internal Audit" rev A, dated 6/6/2024 does not ensure that internal audits of your management system are adequate. For example,

A) The procedure does not ensure that internal audits are conducted by auditors who do not have direct responsibility for the area being audited. For example, all audits conducted in 2024 and 2025 were conducted by a team of auditors which includes your Quality Manager (b) (6), (b) (7)(C) The documentation does not designate which areas are covered by which member of the team to ensure that they're not auditing areas they

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control. This includes the coverage of document controls which was covered during (b) (4) of 2025. .

B) The audits were not completed per your schedule and without a documented deviation. For example, 6 areas under management controls were scheduled for (b) (4) of 2025 and have not been completed as of 2/11/2026.

OBSERVATION 6

Records of the results of evaluation, selection, monitoring and re-evaluation of supplier capability or performance were not adequately maintained.

Specifically, your procedure SOP-0005 "Purchasing" rev A, dated 9/9/2024 and corporate procedure P-840 "Control of External Suppliers" rev 4, dated 11/26/24 does not ensure that your suppliers are reviewed, approved, and evaluated. For example,

A) Section 6.1 of SOP-0005, states that any supplier on the "AVL prior to the initial release of this procedure are considered established are exempt from the selection and qualification process". No review was done to ensure those suppliers were able to meet requirements associated with your devices.

B) Scorecards prepared by corporate are to be presented to your quality manager for review. According to your Quality Manager (b) (6), (b) (7)(C), no (b) (4) scorecards were provided in 2025.

C) Your firm has not set a set time frame for evaluations. According to section 8.1 in SOP-0005, "Purchasing and Quality Management perform periodic evaluations" this timeframe has not been defined adequately to ensure suppliers are reviewed at a risk based interval.

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OBSERVATION 7

When product requirements were changed, your firm did not ensure relevant documents were adequately amended and relevant personnel were made aware of the changes.

Specifically, your firm does not have a documented process to ensure that customer related changes do not adversely affect your manufacturing process. For example, for the (b) (4) class 2 device, there have been (b) (4) revisions of changes which has led to (b) (4) engineering change notices (ECNs). The ECN process does not ensure that risk associated with production processes are considered and documented as part of your review.

OBSERVATION 8

The monitoring, measurement, analysis, and improvement processes were not adequately planned and implemented to demonstrate conformity of product, ensure conformity of the quality management system and maintain the effectiveness of the quality management system.

Specifically, monitoring of your firm's business performance is defined in section 2.0 of your Management System Manual as Key Performance Indicators (KPIs). These indicators were not reviewed during your 2025 Management Review Meeting as stated in your manual. Furthermore, the KPIs do not address specifics for device quality instead stating for medical to be "100% Compliance with medical products specification folders".

OBSERVATION 9

The quality manual does not adequately include description of the interaction between processes of the quality management system.

Specifically, your "Management System Manual" rev L, dated Aug. 9, 2023, is not adequate to fully define your operations. For example,

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A) Your manual has not been updated to reflect updates to your organization structure. This includes updating specifics as personnel changes or defining what activities are completed at your corporate location verses this manufacturing site.

B) Your manual does not reference all responsibilities of your quality system. For example, your quality manual does not reference process validation.

C) Your manual was not updated as procedures were changed. For example, the procedure numbers were not updated within the quality manual. According to your quality manager ((b) (6), (b) (7)(C), all procedure numbers that start with a (b) (4) are corporate procedures while the procedures associated with this location start with "SOP". There are no procedures that start with "SOP" included in the manual.

***DATES OF INSPECTION**
2/04/2026(Wed), 2/05/2026(Thu), 2/09/2026(Mon), 2/10/2026(Tue), 2/11/2026(Wed), 2/13/2026(Fri), 2/17/2026(Tue)

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Annotations to Observations

Observation 1: Promised to correct

Observation 2: Under consideration

Observation 3: Promised to correct

Observation 4: Promised to correct

Observation 5: Promised to correct

Observation 6: Promised to correct

Observation 7: Promised to correct

Observation 8: Promised to correct

Observation 9: 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."