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	2/25/2026-3/2/2026*
	FEI NUMBER 1824736

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Lee J. Morris, President

FIRM NAME	STREET ADDRESS
Jardon Eye Prosthetics, Inc.	15920 W 12 Mile Rd
CITY, STATE, ZIP CODE, COUNTRY Southfield, MI 48076-3047	TYPE ESTABLISHMENT INSPECTED Medical Device

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

One or more processes for risk management in product realization have not been documented.

Specifically,

Your firm has not documented the risk management process for your class II ophthalmic conformers. The following risk management activities have not been documented: identification of known hazards, risk control measures, and post-production risk management. On 2/25/26, L.M., President, confirmed no such documentation exists.

OBSERVATION 2

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 firm lacks a procedure for managing nonconforming product. On 2/25/26, (b) (6), (b) (7)(C) Office Manager,

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confirmed no such documentation exists. When scrap or rework occurs, documentation is limited to recording the quantity rejected/reworked on the Production Routing Sheet, with no additional details captured. This current process does not document the evaluation of nonconformances or the determination of whether an investigation is needed.

OBSERVATION 3

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

Specifically,

a. Your standard operating procedure *Year End - Quality Auditing* (Form: 1245; Rev. B; Effective Date: Unknown) does not ensure that internal audits are conducted at planned intervals. For example, I requested objective evidence of quality audits from the previous three years, including dates, auditors, and quality management system areas covered. L.M., President, confirmed that no such documentation exists.

b. Your standard operating procedure *Year End - Quality Auditing* (Form: 1245; Rev. B; Effective Date: Unknown) does not require all quality management system areas to be included within your internal audits. For example, the procedure does not require the review to include design and development, purchasing, corrective actions, preventive actions, and document controls.

c. Your standard operating procedure *Year End - Quality Auditing* (Form: 1245; Rev. B; Effective Date: Unknown) does not require auditor independence from the area being audited.

OBSERVATION 4

Criteria for the evaluation and selection of suppliers were not established.

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Specifically,

Your standard operating procedure *Vendor and Supplier Approval* (Form: 1910; Rev. B; Effective Date: 6/11/10) does not adequately document the requirements for the evaluation and selection of suppliers. Your firm was unable to provide documented evidence demonstrating that suppliers were evaluated and selected based on their ability to meet specified requirements.

Additionally, your firm has not defined the type and extent of controls to be exercised over suppliers based on evaluation results. This deficiency applies to all suppliers, including those providing raw material for your class II ophthalmic conformers.

OBSERVATION 5

Requirements for infrastructure maintenance activities that can affect product quality, including the interval of performing the maintenance activities, have not been adequately documented.

Specifically,

Your standard operating procedure *Equipment Maintenance* (Form 1012, Rev. C; Effective Date: Unknown) does not adequately establish maintenance requirements or schedules. The procedure states, *"None of the equipment used in the manufacturing process for Lucite and Silicone products require any maintenance and none of the equipment would adversely effect the quality of the products that are manufactured."*

However, your firm does perform maintenance activities. Specifically, (b) (4) on (b) (4) and (b) (4) on (b) (4) and (b) (4) (b) (4) machines are replaced when they wear out. This equipment is used in manufacturing your class II ophthalmic conformers. These replacement activities constitute

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maintenance that is not adequately described in a maintenance schedule. Additionally, these activities are not documented, including the date performed and the individual(s) who performed them.

OBSERVATION 6

Documents required by the quality management system have not been adequately controlled.

Specifically,

Your standard operating procedure *Change Control Document* (Form: 1247; Rev. B; Effective Date: Unknown) does not adequately ensure the control of QMS documents. This procedure requires any and all changes made to a document to be recorded on the *Document Approval Log* (Form #1110). However, I attempted to identify the effective date of standard operating procedure *Year End - Quality Auditing* (Form: 1245; Rev. B) only to discover this procedure is not captured within the *Document Approval Log*.

OBSERVATION 7

Procedures for management review have not been documented.

Specifically,

Your firm lacks a procedure for conducting management reviews. Consequently, management reviews have not been conducted. On 2/25/26, (b) (6), (b) (7)(C) Office Manager, confirmed this to be true.

OBSERVATION 8

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

Specifically,

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Your firm does not have documentation of the appointment of a management representative. On 2/25/26, (b) (6), (b) (7)(C) Office Manager, confirmed no such documentation exists.

***DATES OF INSPECTION**
2/25/2026(Wed), 2/26/2026(Thu), 3/02/2026(Mon)

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Annotations to Observations

Observation 1: Not annotated

Observation 2: Not annotated

Observation 3: Not annotated

Observation 4: Not annotated

Observation 5: Not annotated

Observation 6: Not annotated

Observation 7: Not annotated

Observation 8: 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."