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	1/5/2026-1/12/2026* FEI NUMBER 3029740697

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
David Mason, General Manager

FIRM NAME	STREET ADDRESS
ZIIP INC	2495 Estand Way
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Pleasant Hill, CA 94523-3911	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 receiving, reviewing, and evaluating complaints by a formally designated unit have not been adequately established.

Specifically, the investigations for 26 ZIIP HALO complaints reviewed were not adequately documented, or a rationale documented for why no investigation was necessary, per Complaint Management Procedure, SOP-028, Rev D, effective 3/3/2021 - 12/30/2025, including:

a) Sixteen complaints reporting electric shocks, burns, pain, swelling, muscle twitching, stabbing sensations, headaches, vein engorgement and/or facial immobility during or after ZIIP HALO device use.

b) Ten complaints reporting overheating, burning, smoking, and/or melting of the ZIIP HALO device.

Additionally, nine of these complaint records identify that "human review" is required for MDR determination or severity assessments; however, final reportability determinations were not documented for these nine complaints.

OBSERVATION 2

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Procedures for corrective and preventive action have not been adequately established.

Specifically, five of five closed CAPAs reviewed were inadequate per the firm's Corrective and Preventive Action Procedure, SOP-022, Version B, effective 3/21/2019 - 12/31/2025. For example,

1. CAPA 22, initiated 10/7/2024 to address ZIIP HALO overheating, charging issues, and melted charging ports, identified that gel ingress into the charging port can lead to excessive current flow; however,
   a. A risk assessment was not performed to determine if containment actions were required for units in the field;
   b. The corrective action plan indicates a long-term solution is a design change to the lightband but the CAPA was closed before initiating this design change;
   c. The CAPA does not include an effectiveness check.

   Since initial distribution of ZIIP devices in May 2022, the firm has received approximately 123 complaints related to overheating, melting, smoking or burning of the ZIIP HALO.
2. CAPA 33, initiated 7/13/2025 to address inadequate complaint handling procedures, was closed without evidence of plans to complete an effectiveness check.
3. CAPA 47, initiated 7/14/2025 to address deficiencies with acceptance activities, identified production operator training as a corrective action but the CAPA was closed on 12/31/2025 without evidence of employee training or verification of effectiveness.
4. CAPA 49, initiated 7/14/2025 to address lack of consistent CAPA effectiveness checks, identifies an immediate action is to review a representative sample of recent CAPAs to confirm full closure and re-open CAPA as needed; however, the CAPA did not document evidence of this review and was closed without documented plans to complete an effectiveness check.
5. CAPA 50, initiated 7/14/2025 to address inadequate design change activities, identified that the only corrective action was to review and retrain personnel; however, this CAPA was closed without performing employee training or documenting plans for completing an effectiveness check.

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OBSERVATION 3

Design verification does not confirm that design output meets design input requirements.

Specifically,

1. The Quality Manager stated the objective evidence corresponding to *Verification Report 199001-008*, dated 3/31/2021, which verified multiple ZIIP HALO design specifications was missing and unavailable for review. As such, the firm could not provide evidence that the following design inputs—identified as being critical to safety—have been verified:
   - The voltage at the electrodes shall not exceed (b) (4) Volts at any given instant.
   - The current supplied by the unit at the electrodes shall not exceed (b) (4) microamperes at any given instant.
   - The unit shall monitor the battery temperature when it is on.
   - The unit shall stop any treatment protocols if the battery temperature exceeds (b) (4)

   The ZIIP 2.0 Hazard Analysis / Risk Management Plan and Report identifies that maximum output voltage delivered to the electrodes may lead to cytotoxicity, irritation, pain, skin burns, raised welts, numbness/tingling, and spasm/tetany. Since initial distribution of ZIIP devices in May 2022, the firm has received approximately 453 complaints reporting injuries or adverse health effects during or after use of the ZIIP HALO device, including pain, electrical shocks or stronger than expected electrical sensations, muscle twitching, skin burns, vein engorgement, headaches, and skin irritation.
2. The General Manager stated ZIIP HALO software verification was covered within Verification Report, 199001-008; however, the firmware (build) version tested was not documented within this report or the corresponding protocol.
3. ZIIP HALO Design input ZIIP-DIM-038 states, (b) (4) (b) (4) however, (b) (4) Report (b) (4) dated (b) (4) provided as evidence of this testing, did not provide a sample size rationale for testing only (b) (4) ZIIP HALO device and did not include evidence of review and approval by ZIIP personnel.

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OBSERVATION 4

Procedures for design validation have not been adequately established.

Specifically, the firm's Design Verification & Validation Procedure, SOP-14, identify testing of product under actual or simulated use conditions as a fundamental requirement of design validation; however, the ZIIP 2.0 Validation Report, Document Number: 199001-006, released 3/31/2021, validating the design of the ZIIP HALO was inadequate per the following:

a) The User Guide states, "For even more radiance, we offer a range of Conductive Gels on our website containing active ingredients. These gels can be used as an alternative to the Electric Complex Gel." However, testing to ensure the Golden Gel, Clear Gel, Silver Gel, and Crystal Gel are compatible with the ZIIP HALO and meet user needs and intended uses was not performed.

b) Testing performed as part of Validation Report 199001-006 was conducted solely by the firm's General Manager, and a rationale for the sample size of (b) (4) "Tester" was not documented within the corresponding protocol or this report.

OBSERVATION 5

Procedures for design change have not been adequately established.

Specifically, the Design Controls Procedure, SOP-13, requires design changes to be thoroughly reviewed for the need to repeat design verification and/or validation testing. However,

1. In October 2025, new treatment protocols were added to the app used with the ZIIP HALO device; however, this change was not documented per SOP-13 or reviewed for the need to perform design verification and/or validation, including software verification and/or validation, to ensure the app's treatment protocols provide the correct frequencies, waveforms, currents, and durations. Furthermore, the firm could not provide evidence that the details of any of the App's revisions were adequately documented.

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2. Since initial distribution of the ZIIP HALO device in May 2023, there have been (b) (4) firmware revisions; however, the details of these changes were not documented, nor were these revisions reviewed for the need to perform design verification and/or validation. For example, the Firmware Revision Log identifies that Build 28, Revision 1.0.27, released 9/13/2023, updated DAC Offset checks during programming, which the General Manager explained was an activity that needs to be done during (b) (4) programming of the device to ensure the electrical current's output is correct; however, additional information surrounding this update was not documented or provided.
3. The design change documented within DCN 78, initiated 1/1/2026 to add a (b) (4) charging port plug to the ZIIP HALO, was not verified and/or validated to ensure the part is effective in preventing ingress of conductive gel into the charging port. Furthermore, the change was not evaluated to determine if a regulatory submission was required, despite SOP-13 requiring all design changes to be reviewed for the need to report to applicable regulatory bodies. The (b) (4) charging port plug was added to prevent unintended electrical pathways and excessive current flow which can lead to device overheating, smoking, and melting. This design change was implemented in November 2024 but was not documented within DCN78 or elsewhere until 1/1/2026.

OBSERVATION 6

Risk analysis is inadequate.

Specifically, the ZIIP 2.0 Hazard Analysis / Risk Management Plan and Report is inadequate per the following:

a) Hazard ID ZIIP-HA-032 identifies the consequences of device overheating as "brief, insignificant warming, damage to electronics; device shutdown" and severity as "negligible;" however, ten complaints reviewed during this inspection reported smoking, burning, or melting of ZIIP HALO devices, including Complaint 97540550 which identified device smoking as a "serious malfunction which could pose fire/safety hazard and potentially cause serious injuries."
b) Hazard ID ZIIP-HA-003—the hazard covering fluid ingress into the ZIIP HALO charging port—

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identifies the probability of occurring as "remote;" however, CAPA 22, initiated 10/7/2024 to address gel intrusion, states, "Varying degrees of customer complaints (device not turning on, not charging, overheating, smoking port, melted port, etc.) have been found to be related to the intrusion of gel into the charging port." Since March 2024, the firm has received 985 verified complaints found to have gel, material, or moisture in the charging port.

OBSERVATION 7

An MDR report was not submitted within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Specifically, Complaint 97540550, reporting a burning smell coming from the ZIIP HALO during charging, states "Device smoking indicates a serious malfunction that could pose fire/safety hazard and potentially cause serious injury if recurrence occurred;" however, no MDR was submitted for this complaint, received 7/30/2023, or seven similar complaints reporting device burning, melting, smoking, or overheating which were received after 7/30/2023, including:

1. Complaint 97537231, received 8/5/2023
2. Complaint 101227614, received 5/8/2024
3. Complaint 109765994, received 6/27/2024
4. Complaint 114381725, received 7/24/2024
5. Complaint 133307241, received 11/18/2024
6. Complaint 150108630, received 2/15/2025
7. Complaint 154680693, received 3/16/2025

OBSERVATION 8

A device master record has not been maintained.

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Specifically, the Quality Manager stated the firm has not maintained a Device Master Record for the ZIIP HALO device, required by the firm's Quality Policy Manual, QM-1.

***DATES OF INSPECTION**

1/05/2026(Mon), 1/06/2026(Tue), 1/07/2026(Wed), 1/08/2026(Thu), 1/12/2026(Mon)

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Annotations to Observations

Observation 1:

Observation 2:

Observation 3:

Observation 4:

Observation 5:

Observation 6:

Observation 7:

Observation 8:

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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."