DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Harbor Bay Parkway Alameda, CA 94502-7070 (510)337-6700 Fax:(510)337-6702	12/2/2025-12/10/2025* FEI NUMBER 3013870241

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Andrew W. Kaps, President

FIRM NAME	STREET ADDRESS
Sauna Works, Inc	1077 Eastshore Hwy
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Berkeley, CA 94710-1011	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 WE OBSERVED:

OBSERVATION 1

Procedures for design control have not been established.

Specifically, your firm has not established design control procedures for the Clearlight Red Light Therapy device to control the design and development process of the device to ensure that specified design requirements are met. Additionally, no specifications have been defined for the components used in the Red Light Therapy device, including timer components, power supply specifications, LED specifications, and control circuit requirements. Furthermore, your firm failed to document the required design control activities, including design inputs (user needs, intended use, and performance requirements), design outputs (device specifications, drawings, and software requirements), design verification (testing to confirm design outputs meet design inputs), design validation (testing to ensure the device meets user needs and intended use), design changes (documentation and control of design modifications), and risk management procedures and records. Your firm's Vice President of Operations stated that design control procedures have not been established, and that your firm does not have records documenting design control activities.

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	Nga T Ho, Investigator Richard E Evoy, Investigator Bryce A May, Investigator	X Bryce A May Investigator Signed By: 2000816325 Date Signed: 12-10-2025 11:18:03	12/10/2025

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OBSERVATION 2

Procedures for receiving, reviewing, and evaluating complaints by a formally designated unit have not been established.

Specifically,

A. Your firm failed to establish written procedures for complaint handling, including procedures for formal complaint evaluation and investigation decision-making, evaluation for Medical Device Reporting reportability, and investigation of possible failure of device, packaging, or labeling. Your firm's Vice President of Operations stated that complaint handling procedures have not been established.

B. Your firm failed to review and evaluate complaints for investigation requirements for all 13 complaint records reviewed. For example, (b) (4) (b) (4) related to customer complaints about the red light were not evaluated to determine if investigation is necessary. Review of complaint files revealed multiple cases involving red light therapy devices with similar failure modes-red light not working or red light timer shutting down earlier than intended- that were handled as individual customer service issues rather than formal complaints requiring evaluations.

C. Your firm did not evaluate complaints to determine if they represent events that must be reported to FDA as part of Medical Device Reporting requirements. The recurring timer malfunctions and device failures were not assessed for potential safety implications or reporting requirements. Your firm's Vice President of Operations stated that your firm does not evaluate complaints for MDR reportability.

OBSERVATION 3

Procedures for corrective and preventive action have not been established.

Specifically, your firm failed to establish procedures for analyzing, investigating, and identifying actions

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needed to correct and prevent recurrence of nonconforming product and other quality problems through the systematic analysis of processes, work operations, quality audit reports, quality records, complaints, and returned products. Additionally, your firm does not maintain records documenting these CAPA inputs, including complaint data, nonconformance trends, audit findings, process performance indicators, and returned product analysis, which prevents effective identification of systemic quality issues and implementation of appropriate corrective and preventive actions to eliminate the causes of actual and potential nonconformities. Your firm's Vice President of Operations stated that corrective and preventive action procedures have not been established.

OBSERVATION 4

Written MDR procedures have not been developed.

Specifically, your firm failed to define and implement written procedures for the identification, evaluation, and reporting of medical device events. During the inspection, no written procedures were provided that address the requirements for medical device reporting, including documented procedures for identifying reportable events, evaluating device malfunctions and adverse events for reporting criteria, determining reportability timelines, ensuring timely submission of medical device reports (MDRs) to FDA, training personnel on MDR requirements, maintaining MDR records, or conducting periodic reviews of complaint data to identify potential reportable events. The absence of written MDR procedures resulted in the failure to evaluate and report a device malfunction that, if it were to recur, could potentially result in serious injury to customers, as documented in (b) (4) which described a customer who was electrocuted during use of your firm's sauna when the back panel had exposed wiring. Additionally, multiple device malfunctions involving the Clearlight Red Light Therapy device were not evaluated for MDR reportability, including timer failures and power supply issues documented in complaint cases (b) (4) and (b) (4) Your firm's Vice President of Operations confirmed that MDR procedures have not been established, demonstrating a systemic gap in regulatory compliance infrastructure.

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OBSERVATION 5

Procedures to ensure that all purchased or otherwise received product and services conform to specified requirements have not been established.

Specifically, your firm failed to establish procedures that define the requirements which must be met by suppliers of primary components used in the Clearlight Red Light Therapy device, including but not limited to LED lights, power cords, timer components, and power supplies. Your firm's Vice President of Operations stated that supplier control procedures have not been established. Additionally, there is no documentation demonstrating that suppliers have been evaluated and selected based on their ability to meet specified requirements, nor is there evidence of ongoing supplier qualification or performance monitoring to ensure continued compliance with component specifications and quality standards.

OBSERVATION 6

Procedures for acceptance of incoming product have not been established.

Specifically, your firm failed to establish written procedures for the acceptance of incoming Clearlight Red Light Therapy devices to ensure they meet specified requirements before distribution. Additionally, your firm does not maintain records documenting the acceptance activities performed on incoming devices, including any inspection, testing, or verification activities conducted to confirm device conformance to specifications prior to release for distribution. Your firm's Vice President of Operations stated that incoming inspection/acceptance procedures have not been established, and that your firm does not conduct and/or document incoming inspection activities for your Clearlight Red Light Therapy devices.

OBSERVATION 7

Procedures to control labeling activities have not been established.

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Specifically, your firm failed to establish and maintain procedures to control labeling activities to prevent mixups and to ensure that only device labeling having the correct content is used for each device. Your firm's Vice President of Operations stated that labeling control procedures have not been established. Additionally, your firm failed to include a unique device identifier (UDI) on the label of the Clearlight Red Light Therapy device and failed to establish procedures for UDI compliance. During the inspection, no written procedures were provided that address the control of labeling activities for the Clearlight Red Light Therapy device, including procedures for labeling design approval, labeling storage and handling, prevention of labeling mixups, verification of correct labeling content prior to use, control of labeling changes, and ensuring that only approved labeling is applied to devices. Furthermore, examination of the primary product label revealed the absence of a UDI, which is required for Class II medical devices, and the absence of lot number identification, which is necessary for device traceability and recall purposes. No procedures were established for UDI assignment, formatting, placement on device labels, submission of device information to the Global Unique Device Identification Database (GUDID), or for lot number assignment and labeling. Your firm also lacks procedures for inspecting labeling for legibility, adhesion, and correct placement on devices, as well as procedures for controlling labeling inventory to prevent the use of obsolete or incorrect labeling materials. The absence of labeling control procedures, UDI compliance, and lot number identification creates a risk that devices may be labeled with incorrect, outdated, or unapproved labeling content, and prevents proper device identification, traceability, and recall capability.

OBSERVATION 8

Procedures for management review have not been established.

Specifically, your firm failed to establish written procedures for conducting management reviews of the

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quality system to ensure its continuing suitability and effectiveness. Additionally, no formal management reviews have been documented within the last five years, demonstrating a lack of ongoing management oversight and evaluation of quality system performance, effectiveness of corrective and preventive actions, and adequacy of resources allocated to maintain product quality and regulatory compliance.

OBSERVATION 9

Procedures for quality audits have not been established.

Specifically, your firm failed to establish procedures and maintain an adequate internal quality audit program to verify whether quality activities and related results comply with planned arrangements and to determine the effectiveness of the quality system. During the inspection, no written procedures were provided for conducting internal quality audits, and no evidence was found of any internal audits being performed to assess compliance with the Quality System Regulation. Your firm lacks documented procedures for audit planning, scheduling, conducting audits, reporting audit findings, implementing corrective actions, and follow-up verification of corrective action effectiveness. Additionally, no records were provided demonstrating that internal audits have been conducted to evaluate the adequacy and effectiveness of quality system elements including design controls, document controls, purchasing, production and process controls, inspection and testing, complaint handling, corrective and preventive actions, and records management.

***DATES OF INSPECTION**

12/02/2025(Tue), 12/04/2025(Thu), 12/05/2025(Fri), 12/09/2025(Tue), 12/10/2025(Wed)

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X Richard E Evoy
Investigator
Signed By: RICHARD E. EVOY -S
Date Signed: 12-10-2025 11:18:59

X Nga T Ho
Investigator
Signed By: 2004123592
Date Signed: 12-10-2025 11:20:42

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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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Annotations to Observations

Observation 9:

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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."