

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER 19701 Fairchild Irvine, CA 92612-2445 (949) 608-2900 Fax: (949) 608-4417		DATE(S) OF INSPECTION 1/7/2026-1/9/2026 FEI NUMBER 3020749939	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Benjamin K Li, Owner			
FIRM NAME Encore Laboratory		STREET ADDRESS 1520 Brookhollow Dr Ste 38	
CITY, STATE, ZIP CODE, COUNTRY Santa Ana, CA 92705-5422		TYPE ESTABLISHMENT INSPECTED 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. <i>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.</i>			
DURING AN INSPECTION OF YOUR FIRM I OBSERVED: OBSERVATION 1 The device history record does not demonstrate that the device was manufactured in accordance with the device master record and 21 CFR 820. Specifically, 11 of 11 device history records (DHRs) reviewed during this inspection of your firm failed to demonstrate that your firm's night guards are manufactured in accordance with the device master record (DMR) and 21 CFR 820.184. Your firm's <i>SOP-826 Manufacturing Procedure, Revision 1, Approval Date 05/08/2024</i>, identifies DHR documentation requirements in Section 3.2 <i>Device History Record (DHR)</i> and defines DHR and Work Order (WO) as the records ... to demonstrate that the device is manufactured in accordance with the DMR and the requirements of the part. Your firm's <i>SPEC-004 Device Master Record – Night Guards, Revision 2, Approval Date 07/16/2024</i>, identifies <i>WO-001 Work Order Traveler – Night Guards Impressions</i> as a manufacturing instruction document, which contains fields to capture information required by your DMR (e.g., UDI, manufacturing date, final product acceptance and release, etc.). However, your firm uses an unapproved (b) (4) to record DHRs. The (b) (4) does not require the same information be captured as what is shown in <i>WO-001, SOP-826</i>, or 21 CFR 820.184.			
AMENDMENT 1			
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Alexandria L Capuano, Investigator		DATE ISSUED 1/12/2026
	Alexandria L. Capuano Investigator Signed By: Alexandria L. Capuano Date Signed: 01-12-2026 11:37:07 X _____		

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OBSERVATION 2 Products that do not conform to specifications are not adequately controlled. Specifically, Your firm's procedure, <i>SOP-830 Nonconformance Management Procedure, Revision 1, Approval Date 02/13/2024</i>, defines the requirements for <i>controlling the identification, segregation, evaluation and dispositioning of suspected or known product related non-conformances</i>, and identifies form, <i>F-830 Nonconformance Report</i>, as the appropriate form to document nonconforming product events. However, 11 of 11 nonconformance records reviewed used an unapproved (b) (4) to record nonconforming product information. The (b) (4) does not require the same information be captured as what is identified in your firm's procedure and form.			
OBSERVATION 3 Procedures for receiving, reviewing, and evaluating complaints by a formally designated unit have not been adequately established. Specifically, Your firm's complaint handling procedure, <i>SOP-822 Complaint Handling Procedure, Revision 1, Approval Date 01/03/2024</i>, is not adequately established. For example: a) Your firm's procedure lists <i>Complaint Form, F-822-XXX</i> under Section 2.3 <i>Quality Records</i> and Section 3.5 <i>Complaint Form</i> states that complaint handling information shall be recorded in the complaint form. However, your firm uses an unapproved (b) (4) to record complaint handling information. The (b) (4) does not require the same information be captured as what is shown on the <i>Complaint Form</i> referenced in your firm's procedure. b) Section 3.4 <i>Complaint Handling Unit</i> of your firm's procedure states that "...complaints are evaluated to determine whether the complaint represents an event which is required to be reported to regulatory authorities". However, 11 out of 11 complaints reviewed during the			
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inspection of your firm did not contain an evaluation to determine whether the complaint represents an event which is required to be reported. c) Section 3.7 <i>Handling Complaint Related Products</i> of your firm's procedure states that "If a complaint is not investigated, justification shall be documented". However, 11 out of 11 complaints reviewed during the inspection of your firm were not investigated and did not contain justification for why they were not investigated. d) Your firm's procedure doe not adequately define the following processes: determining if feedback is a complaint (Section 3.2 <i>Initial Event Evaluation</i>), reviewing and evaluating complaints to determine if an investigation is necessary (Section 3.6 <i>Complaint Investigation</i>), and justification for investigations not being completed (Section 3.7 <i>Handling Complaint Related Products</i>).			
OBSERVATION 4 The labels of the medical device(s) do not bear a unique device identifier (UDI) that meet the requirements of 801 Subpart B and 21 CFR 830. Specifically, Your firm does not have a UDI for the soft (N230) or hard (N210) models of your firm's night guard, enCore Guard (K241369), and has been manufacturing and distributing these devices without a UDI since August 2024. Your firm has manufactured and distributed (b) (4) f the hard (N210) model and (b) (4) of the soft (N230) model of these devices since 2024. Additionally, your firm was issued a UDI for the hybrid (N220) model of your firm's night guard on 12/31/2025. However, your firm had previously been manufacturing and distributing this device without a UDI since August 2024. Your firm has manufactured and distributed (b) (4) of these devices since 2024.			
OBSERVATION 5 Quality audits have not been performed.			
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Manufacturer

Specifically,

Your firm's procedure, *SOP-824 Internal Audit Procedure, Revision 1, Approval Date 01/09/2024*, states that "The encore Quality System will be audited (b) (4) at a minimum". On 01/07/2026, your firm's Consultant (b) (6), (b) confirmed that there have been no audits of your firm and that it is an action item that your firm has noted. On 01/09/2025, your firm's Owner confirmed that you have had no internal audits since your device was released for distribution on August 2024.

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Annotations to Observations

Observation 1:

Observation 2:

Observation 3:

Observation 4:

Observation 5:

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1/12/2026

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."