

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER 1201 Harbor Bay Parkway Alameda, CA 94502-7070 (510) 337-6700 Fax: (510) 337-6702		DATE(S) OF INSPECTION 1/9/2026-1/15/2026* FEI NUMBER 3017823876	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Eitan Konstantino, CEO & President			
FIRM NAME Expanse Medical Inc.		STREET ADDRESS 7060 Koll Center Pkwy	
CITY, STATE, ZIP CODE, COUNTRY Pleasanton, CA 94566-3106		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 Procedures for design validation have not been adequately established. Specifically, Section 10.2 of the firm's Design Control Procedure, SOP020, Rev B, effective 5/6/2024, states, "All design and development validations will be completed before full commercial release to the customer;" however, The (b)(4) (b)(4) System Project Plan identifies "Design Validation Plan" as a deliverable; however, the Design Validation Plan, VP041, Rev A, and corresponding report, VR049, Rev A, summarizing the firm's design validation activities for the (b)(4) (b)(4) System, were provided as drafts. The Usability Report, (b)(4) (b)(4) System, TR083, Rev A, provided as one of the firm's design validation activities, was in draft at the time of this inspection, and physician feedback considered as part of usability testing was not fully documented for all physicians identified within the report. The firm has not yet performed its Phase 4 Design Review covering design validation activities for the (b)(4) (b)(4) System, required per SOP020. Since May 2024, the firm has distributed approximately (b)(4) devices, approximately (b)(4) of which have been used on patients.			
SEE REVERSE OF THIS PAGE		EMPLOYEE(S) SIGNATURE Sara M Onyango, Investigator Sara M Onyango Investigator Signed By: SARA M. ONYANGO - Date Signed: 01-15-2026 164126 X	
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OBSERVATION 2 Procedures for receiving, reviewing, and evaluating complaints by a formally designated unit have not been adequately established. Specifically, all seven (b)(4) (b)(4) System complaints received by the firm since August 2024 were not evaluated to determine if the events require medical device reporting per Complaint Management, SOP025, Rev A, effective 7/12/2021, which requires RA/QA to review each complaint for reportability using the Complaint / Adverse Event Criteria Review Form, FM025-3.			
OBSERVATION 3 The information required by the Global Unique Device Identification Database for each medical device version or model required to bear a unique device identifier (UDI) was not provided. Specifically, the Head of QA/RA stated her firm had not taken the steps necessary to submit the six varieties of the (b)(4) (b)(4) System, a Class II medical device, to (b)(4).			
*DATES OF INSPECTION 1/09/2026(Fri), 1/13/2026(Tue), 1/14/2026(Wed), 1/15/2026(Thu)			
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Annotations to Observations (b) (4) Observation 1: Promised to correct Observation 2: Promised to correct Observation 3: Promised to correct (b) (4)			
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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."