

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER 10903 New Hampshire Ave, Bldg66-3513 Silver Spring, MD 20993-0002 (301)796-5490 Fax: (301)847-8136		DATE(S) OF INSPECTION 5/12/2025-5/16/2025 FEI NUMBER 3021836309	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Gregory S. Plamondon, Chief Operating Officer			
FIRM NAME SALUDA MEDICAL PTY. LTD.		STREET ADDRESS 5 Eden Park Dr	
CITY, STATE, ZIP CODE, COUNTRY Macquarie Park, New South Wales, 2113 Australia		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 to control environmental conditions have not been adequately established. Specifically, Since January 2023, your firm failed to re-certify your ISO Class 7 cleanroom according to your procedures and validation protocol, in which Class III medical devices used for spinal cord stimulation are manufactured. Your firm failed to follow your procedure, D100689, Microbial and Environmental Monitoring Procedure, Rev. 9, Effective Date: 10/Sep/2024, in that re-certification of the cleanroom has not been performed annually as described in your cleanroom validation protocol. As stated in the cleanroom validation protocol, Saluda Medical Cleanroom Complex at Rest Annual AG&G Testing, Section 5.2, test procedures, "the test must be performed with all doors closed and in working condition." On 05/13/2025, I observed at least ten (10) individuals manufacturing Evoke CAP12X Lead Extensions in a designated ISO Class 7 cleanroom, which has not been re-certified since January 2023 under working conditions.			
OBSERVATION 2			
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Marvin A Marenco, Investigator		DATE ISSUED 5/16/2025
	Marvin A Marenco Investigator Signed By: MARVIN A. MARENCO -S Date Signed: 05-16-2025 013727		

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Production processes were not developed and conducted to ensure that a device conforms to its specifications. Specifically, a)Your firm failed to follow procedure, ENG-WI-006061, Weld Pull Test Work Instruction, Approval Date: 20/Jun/2022. For example: 1.On 15/May/2025, I observed two (2) production operators manufacturing Evoke CAP12X Lead Extensions, a Class III medical device used for spinal cord stimulation, conduct a weld pull test improperly according to your procedure. Both production operators failed to complete step 2, The measurements obtained were recorded on document, PROD-RPT-006063, Weld Pull Force Test Log, Rev. 7, Approved Date: 20/Jun/2022, without the force gauge reading zero values before conducting the pull test. b)Your firm failed to follow procedure, PROD-WI-005821, Lead Extension Proximal Welding Work Instruction, Rev. 17, Effective Date: 04/Mar/2024. For example: 2.On 15/May/2025, I observed one (1) production operator manufacturing Evoke CAP12X Lead Extensions, a Class III medical device used for spinal cord stimulation, fail to record weld pull test results from the beginning of their shift on document, PROD-RPT-006063, Weld Pull Force Test Log, Rev. 7, Approved Date: 20/Jun/2022. c)Your firm failed to develop adequate procedures to ensure measurements obtained from the Weld Pull Force Test are properly obtained. For example, your procedure, ENG-WI-006061, Weld Pull Test Work Instruction, Approval Date: 20/Jun/2022, fails to provide instructions on how to properly affix the force gauge to the test table before conducting the Weld Pull Force Test.					
SEE REVERSE OF THIS PAGE		<table style="width: 100%; border: none;"> <tr> <td style="width: 60%; border: none; vertical-align: top;"> EMPLOYEE(S) SIGNATURE Marvin A Marenco, Investigator </td> <td style="width: 40%; border: none; vertical-align: top; text-align: center;"> Marvin A Marenco Investigator Signed By: MARVIN A. MARENCO-S Date Signed: 05-16-2025 01:57:27 X </td> </tr> </table>		EMPLOYEE(S) SIGNATURE Marvin A Marenco, Investigator	Marvin A Marenco Investigator Signed By: MARVIN A. MARENCO-S Date Signed: 05-16-2025 01:57:27 X
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OBSERVATION 3 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, Your firm failed to follow your procedure, SOP-000025, Regulatory Reporting Procedure, Rev. A, Effective Date: 07/Jan/2025. Since 17/Feb/2025, when your firm closed a Corrective and Preventive Action for late submissions to notifying bodies such as the FDA, your firm has continued to fail to submit MDR reports to the FDA within 30 days of receiving or otherwise becoming aware of a reportable event. For example: a)MDR Complaint 3021836309-2025-00086 was submitted to the FDA on 04/Apr/2025. This MDR was submitted at least 59 days since your firm became aware of a reportable event on 04/Feb/2025. b)MDR Complaint 3021836309-2024-00039 was submitted to the FDA on 20/Feb/2025. This MDR was submitted at least 55 days since your firm became aware of a reportable event on 27/Dec/2024.			
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Annotations to Observations Observation 1: Observation 2: Observation 3:			
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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."