

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER 10903 New Hampshire Avenue Silver Spring, MD 20993 (301) 594-4695 Fax: (301) 594-4715		DATE(S) OF INSPECTION 12/8/2025-12/11/2025 FEI NUMBER 3011221234	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Jong Man Lee, CEO			
FIRM NAME SMC		STREET ADDRESS 30 Daeposandan-ro, Yanchon-eup	
CITY, STATE, ZIP CODE, COUNTRY Gimpo-Si, Gyeonggi-do, 10048 Korea (the Republic of)		TYPE ESTABLISHMENT INSPECTED Manufacturer	
<p>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.</p>			
<p><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></p>			
<p>DURING AN INSPECTION OF YOUR FIRM I OBSERVED:</p> <p>OBSERVATION 1 Procedures for corrective and preventive action have not been adequately established.</p> <p>Specifically, Your firm failed to follow your CAPA procedure as 7 of 7 reviewed CAPA reports identified inadequate root cause analysis, lack of risk analysis, lack of objective evidence of corrective action implementation and effectiveness verification check.</p> <hr/> <p>OBSERVATION 2 Written MDR procedures have not been developed, maintained and implemented.</p> <p>Specifically, Your Vigilance System Procedure, Rev 4, Dated 05/12/2025 provided as a Medical Device Reporting (MDR) procedure does not have written MDR procedure established as per FDA requirements.</p> <hr/> <p>OBSERVATION 3</p>			
AMENDMENT 2			
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Sunita Pandey, Investigator <div style="text-align: right; margin-top: 20px;"> Sunita Pandey Investigator Signed By: 2003030873 Date Signed: 12-31-2025 115141 _____ X </div>		DATE ISSUED 12/31/2025

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<p>Annotations to Observations</p> <p>Observation 1:</p> <p>Observation 2:</p> <p>Observation 3:</p> <p style="text-align: center;">AMENDMENT 2</p>			
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	<div style="text-align: right;"> Sunita Pandey Investigator Signed By: 2003030873 Date Signed: 12-31-2025 11:51:41 X _____ </div>		
FORM FDA 483 (09/08)		PREVIOUS EDITION OBSOLETE	INSPECTIONAL OBSERVATIONS
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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."