

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER 550 W. Jackson Blvd., Suite 800 Chicago, IL 60661-4716 (312) 353-5863 Fax: (312) 596-4187		DATE(S) OF INSPECTION 12/8/2025-12/11/2025 FEI NUMBER 3030438338	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Kevin M. Schwartz, Co-President			
FIRM NAME Hatch Product Development LLC		STREET ADDRESS 2330 Ernie Krueger Cir	
CITY, STATE, ZIP CODE, COUNTRY Waukegan, IL 60087-3224		TYPE ESTABLISHMENT INSPECTED Contract Manufacturer & Distributor	
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 corrective and preventive action have not been adequately established. Specifically, your firm's written procedures—Corrective Action (QCP-005, Rev. 05, 07/07/2024) and Continual Improvement (LSP-005, Rev. 05, 07/07/2024)—apply to all medical devices manufactured by Hatch Product Development LLC, including the class II (b)(4) medical device (Product Code: FRZ, 510(k) exempt). The (b)(4) medical device is intended to be used to assist caregivers and clinics with patient transferring or positioning. Since 2024, Hatch Product Development LLC has distributed — units. Both QCP-005 and LSP-005 govern the corrective and preventive action process. A. QCP-005 governs the identification, issuance, investigation, documentation, effectiveness review, and approval of corrective actions; however, it lacks the requirement to evaluate identified actions to ensure they do not adversely affect the finished device. For example, corrective action record (b)(4) was opened for preventative maintenance and verified as effective with a statement that equipment status appears current. No additional verification was completed. B. QCP-005 requires corrective action record closure to be completed by documenting the closure in the corrective action log and completing section 10 with a signature. However, — corrective action records were documented as closed in the corrective action log but did not have section 10 completed and remain open. C. LSP-005 governs the identification, issuance, documentation, and effectiveness review of			
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Shuana H Xiong, Investigator		DATE ISSUED 12/11/2025 Shuana H Xiong Investigator Signed By: Shuana H. Xiong-S Date Signed: 12-11-2025 13:55:25 X

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preventive actions; however, there is no objective evidence to support that actions were completed, evaluated, and verified effective. For example, preventive action record [REDACTED] was opened for inclusion of a training matrix but lacks the evaluation, verification of effectiveness and completion of documentation. Preventive action record [REDACTED] has remained open since 2023.			
OBSERVATION 2 Procedures for receiving, reviewing, and evaluating complaints by a formally designated unit have not been adequately established. Specifically, your firm's written procedure Customer Satisfaction (CSP-001, Rev. 06, 07/11/2024) applies to all medical devices manufactured by Hatch Product Development LLC, including the class II [REDACTED] medical device (Product Code: FRZ, 510(k) exempt). The [REDACTED] medical device is intended to be used to assist caregivers and clinics with patient transferring or positioning. Since 2024, Hatch Product Development LLC has distributed - [REDACTED] units. CSP-001 governs the complaint handling process and requires all complaint files to be documented in a complaint log with an evaluation for further action and adverse events. However, there is no supporting evidence that evaluations for further action, adverse events, and investigations are completed and documented in a controlled document.			
OBSERVATION 3 Written MDR procedures have not been developed, maintained and implemented. Specifically, your firm contract manufactures and distributes the class II [REDACTED] medical device (Product Code: FRZ, 510(k) exempt). The [REDACTED] medical device is intended to be used to assist caregivers and clinics with patient transferring or positioning. Your firm has not developed, maintained, or implemented an MDR procedure. Since 2024, your firm has distributed - [REDACTED] units.			
OBSERVATION 4			
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Procedures have not been adequately established to control product that does not conform to specified requirements. Specifically, your firm's written procedure Control of Nonconforming Material (QCP-004, Rev. 05, 07/04/2024) applies to all medical devices manufactured by Hatch Product Development LLC, including the class II medical device (Product Code: FRZ, 510(k) exempt). The medical device is intended to be used to assist caregivers and clinics with patient transferring or positioning. Since 2024, Hatch Product Development LLC has distributed units. QCP-004 governs the nonconforming material process and requires review of nonconforming material and, if necessary, conducting an investigation. However, there is no supporting evidence that an evaluation to determine investigation necessity is completed, nor is there evidence that investigations are conducted.			
OBSERVATION 5 Procedures for finished device acceptance have not been adequately established. Specifically, your firm's written procedure Final Inspection (QCP-003, Rev. 06, 11/05/2025 and Rev. 03, 10/31/2023) applies to all medical devices manufactured by Hatch Product Development LLC, including the class II medical device (Product Code: FRZ, 510(k) exempt). The medical device is intended to be used to assist caregivers and clinics with patient transferring or positioning. Since 2024, Hatch Product Development LLC has distributed units. QCP-003 governs the final inspection process before releasing products for distribution and requires final inspection to be performed with a sample size. Your firm claims to perform verification and inspection; however, there is no objective evidence supporting that verification and inspection was completed for distributed finished medical devices.			
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Annotations to Observations Observation 1: Promised to correct Observation 2: Promised to correct Observation 3: Promised to correct Observation 4: Promised to correct Observation 5: Promised to correct			
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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."