DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768	3/10/2026-3/12/2026
	FEI NUMBER 3030492371

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
John R. Gill, President & CEO

FIRM NAME	STREET ADDRESS
The Side Lyer Company LLC	1509 E Colonial Dr Ste 300
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Orlando, FL 32803-4729	Specification Developer

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.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Design and development changes were not reviewed, verified, validated, and approved before implementation.

Specifically,

During the inspection, it was observed that the firm implemented risk control measures on the side lyer positioning system. A (b)(4) was used to reduce the time it takes to install [redacted] on the side lyer, without conducting validation or verification activities to ensure that these changes did not negatively affect the safety and performance of the device.

OBSERVATION 2

Records of risk management activities in product realization were not adequately maintained.

Specifically, Your firm's risk management documentation is incomplete, risk control measures were not implemented, and your firm failed to determine if risk control measures were effective or if residual risk was acceptable,

For example:
The risk analysis of the side lyer positioning system identified that the backrest could become unattached from the backrest holding slots when moving the unit while a patient is using the unit. This could cause harm to the patient or staff at a severity level of - Your Risk management procedure identifies a severity level of - as CRITICAL and may cause death or serious injury. The risk score was identified as -, unacceptable. The action taken for

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Ulysses D Singleton, Investigator	X Ulysses D Singleton Investigator Signed By: ULYSSES D SINGLETON III -S Date Signed: 03-12-2026 12:29:58	3/12/2026

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risk control was to put a pin in to hold the backrest in place, contact the current buyers to provide a new locking pin, and update the user guide. The risk control measure that you implemented was [(b)(4)] The risk management report states that it "unknown" if a new hazard is generated and the residual risk was not evaluated.

OBSERVATION 3

Records needed to demonstrate compliance with applicable regulatory requirements have not been established and maintained.

Specifically, your firm failed to implement and maintain procedures required to be documented by the Quality Management System Regulation.

A. Your firm's procedure, Management Review SOP #CO-014, Rev: 1, Effective Date 1/24/25, states that the for the [(b)(4)], management reviews are conducted [(b)(4)]. The procedure also states that quality performance and the quality management system are reviewed by executive management at [(b)(4)]. Management was not able to provide me with evidence of a management review being held or a review of the quality management system, at any time since the firm began operations in 2022.

B. Your firms's procedure, Internal Audits SOP # CO-007, Rev: 1, Effective Date: 1/24/25, states that each quality system is to be audited [(b)(4)] and approved by management. The audit results are documented on the audit summary. Management was not able to provide with evidence of an audit or any audit results.

OBSERVATION 4

Procedures to ensure that purchased product conforms to specified purchasing information have not been documented.

Specifically,

A. The firm has not established written procedures for purchasing controls to ensure that purchased products and services conform to specified requirements.

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B. The firm has not established procedures for the evaluation and selection of suppliers, contractors, and consultants based on their ability to meet specified requirements, including quality requirements.

C. The firm does not maintain an approved supplier list or records of acceptable suppliers, contractors, and consultants.

D. The firm has not established acceptance procedures to ensure that purchased or otherwise received products conform to specified requirements. No acceptance activities or procedures were observed.

E. Your firm failed to establish documented procedures or agreements to ensure that your contract manufacturer notifies you of changes to processes, equipment, materials, or facilities that could affect product quality.

OBSERVATION 5

Records to provide evidence of conformity to requirements and the effective operation of the quality management system have not been maintained.

Specifically, Your firm does not have documented procedures for monitoring and measurement of product at final acceptance.

Additionally, your firm failed to establish documented procedures defining final inspection and testing activities, acceptance criteria for finished device release and requirements for recording the identity of the person authorizing release of product.

OBSERVATION 6

The necessary competence for personnel performing work that affects product quality has not been determined.

Specifically, your firm is not following its established procedure, Training, SOP CO-012, Rev: 1, Effective Date 1/24/25.

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A. The firm's procedure requires that all employees receive training in the Quality Management System (QMS), Quality Policy, relevant procedures, and have a basic understanding of regulatory requirements. Additionally, Section 6.2.1 requires that all employees must be trained in what constitutes a customer complaint and in the complaint handling procedure. No documentation was available to demonstrate compliance with these requirements.

B. SOP CO-012, Section 6.6.1 requires that following competency or skill training, employees are evaluated by their supervisors or departmental managers to determine the effectiveness of training and results of this evaluation are recorded and kept together with the original training record.

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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

Observation 6: 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."