DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
109 Holton Street Winchester, MA 01890 (781)587-7500 Fax:(781)587-7556	2/4/2026-3/6/2026* FEI NUMBER 3001592626

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Edward L. Ursillo, Director of Quality

FIRM NAME	STREET ADDRESS
Linemaster Switch Corporation	29 Plaine Hill Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Woodstock, CT 06281-2913	Medical Device 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.

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.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

One or more processes for risk management in product realization have not been documented.

Specifically, your firm manufactures foot pedal (b) (4), an accessory device used to control Class IV medical lasers. Your firm failed to document and maintain risk management processes for this device, resulting in uncontrolled risks associated with calibration including unintended laser activation or inadequate laser power delivery.

A) Your firm failed to maintain current risk management records for foot pedal (b) (4). On 02/06/2026, your Director of Engineering could not locate the Design FMEA. After a 2-day search, your firm provided TM-85 Rev B dated February 8, 2011, which has not been updated in 15 years despite known customer failures, design changes, and post-market data indicating calibration-related unintended activation risks, including: (b) (4) affecting calibration (identified 2013), torque affecting calibration (identified 2021) and rework affecting calibration (identified 2023). Approximately (b) (4) units have been distributed ((b) (4)) without current risk evaluation.

B) Your firm failed to create a Process FMEA for foot pedal (b) (4) as required by procedure TM-112 Section 5.3.2, which states: "Process FMEA's are created to assess the highest risk in processing and action is taken to reduce the risk." Your Director of Engineering confirmed on 02/06/2026 that no

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Process FMEA exists for this device.

C) Your firm's risk management procedure TM-112 Rev D does not adequately describe a documented process for risk management in product realization. TM-112 Rev D fails to adequately define how risk management activities are performed and documented, who is responsible for conducting and approving risk management activities, when risk management documentation must be updated, and how post-market data (including complaints, adverse events, and recalls) is incorporated into risk management.

OBSERVATION 2

Product which does not conform to product requirements was not identified and controlled to prevent its unintended use or delivery.

Specifically,
A) During Job (b) (4) , (b) (4) units of (b) (4) , your part number for (b) (4) , (b) (4) accessory devices used to control Class IV medical lasers) manufactured February 2-6, 2026, the supervisor discovered that, after calibration, the assembler had failed to torque (b) (4) . The supervisor had the assembler perform rework to apply torque and recalibrate all (b) (4) units, causing some devices to produce unintended "on" signals. Your firm failed to:

1) Track which specific units had the "on" signal problem
2) Segregate defective units from conforming units during rework and finished device testing
3) Create Material Review Reports (MRR) when the problem was discovered as required by Nonconforming Material Control Procedure Q 006 Rev D3 dated 10/14/2025
4) Complete Q6-12 rework form per Q 006 Rev D3, Section 8.3
5) Document which serial numbers were affected and how they were corrected

Your firm's finished device testing procedures (TM-118 Rev C and QTP/SP-986-13 Rev G) do not include verification there are no unintended "on" signals when the device is at rest.

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Devices with unintended "on" signals when used to control Class IV medical lasers could activate the laser unexpectedly leading to unintentional laser delivery and possible ocular damage or burns. FMEA, TM-85 Rev B, identifies this failure mode as '(b) (4) ."'

B) Your procedure Q 006 Rev D3 (10/14/2025) allows nonconforming product categorized as "reprocessing" to bypass MRR and Q6-12 requirements. The following lots were documented as "reprocessed" and released without adequate control:

1)Lot (b) (4) : 1 unit failed first piece inspection, reprocessed, QC failure shows visual-to-drawing inspection failure, component installed incorrectly, no Q6-12 completed.
2)Lot (b) (4) : 1 unit reprocessed, workmanship defect ((b) (4)), no Q6-12 completed
3)Lot (b) (4) : 1 unit reprocessed – failed finished device testing - no QC test records, no Q6-12 completed
4)Lot (b) (4) : 1 unit reprocessed, failed finished device testing - no QC test records, no Q6-12 completed
5)Lot (b) (4) : 1 unit reprocessed, failed first piece inspection, QC failure shows visual-to-drawing inspection failure, label damaged, no Q6-12 completed

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OBSERVATION 3

Corrective action was not taken to eliminate the cause of nonconformities in order to prevent recurrence.

Specifically,
Section 9.1 of the Nonconforming Material Report Procedure Q 006 Rev D3 requires Customer Requests for Corrective Action be "investigated and answered by Quality Assurance within (20) working days of receipt", however SCAR-00014, dated 11/14/2023 requiring investigation and corrective action was not investigated and evaluated for action.

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SCAR-00014 states that (b) (4) units of the (b) (4), your part number for (b) (4), foot pedal accessory devices used to control Class IV medical lasers, failed the calibration verification test at the customer's facility. The units were returned to Linemaster Switch. Linemaster Switch initiated an internal nonconforming report and identified that the "switches came out of calibration" per MRR #14522.

The customer stated on November 20, 2023 that "the basis of the SCAR is the pedal calibration activity at your facility" and that they "received parts that were out of calibration" according to Linemaster Switch's MMR #14522.

Despite this, your firm continued to reject the SCAR. Your SCAR response on January 26, 2024 shows Root Cause [BLANK] and Corrective Action "NA"."

Foot pedals out of calibration may lead to unintended laser activation or inadequate laser power delivery. Your decision to not investigate and evaluate for action was not commensurate with the potential risk to patients/users.

OBSERVATION 4

Requirements for the work environment, and the procedures to monitor and control the work environment, were not adequately documented where conditions for the work environment can have an adverse effect on product quality.

Specifically,
Your firm has not adequately validated the (b) (4) to prevent calibration drift of the (b) (4), your part number for (b) (4), foot pedal accessory devices used to control Class IV medical lasers, and have not established environmental controls for calibration of the (b) (4) foot switches:

A) (b) (4) was not adequately validated. Request for Engineering Assistance (REA)

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#0120763, dated September 26, 2013, states "(b) (4) " which affects (b) (4) foot switches. (b) (4) is the unintended change in a sensor's output due to temperature fluctuations, causing measurement inaccuracy over time. Your firm implemented software that "(b) (4) ." and claimed this was "validated using TM-83" on September 28, 2013. However, TM-83 tests basic firmware functionality at (b) (4) only and does not include:

1) Testing at multiple temperatures
2) Correlation between temperature and output
3) Demonstration that (b) (4) maintains calibration accuracy across temperature variations
4) Raw data, statistical analysis, or pass/fail criteria specific to (b) (4) performance

B) Your firm has not documented requirements for work environment temperature control for calibration:

1) No temperature-controlled areas for calibration
2) Temperature is not monitored or recorded during calibration
3) Calibration procedure TM-118 Rev C (August 27, 2021) does not specify temperature requirements
4) Quality test procedure QTP SP-986-13 Rev G (September 25, 2013) does not specify temperature requirements
5) PCB boards containing (b) (4) elements are stored (b) (4) away and transported without temperature controls or acclimation requirements

Without adequate validation and environmental controls, your firm cannot demonstrate that devices maintain accurate calibration under temperature variations. For example, in (b) (4) : (b) (4) units (MRRs 14522, 15153, 15266, 15338, 15392, 15407, 15613) passed your calibration testing but failed customer calibration testing.

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Your firm has not investigated whether inadequate (b) (4) validation or lack of environmental controls contributed to these calibration failures.

Risk to Patient/User: Calibration drift can result in unintended laser activation or inadequate laser power delivery.

OBSERVATION 5

Software used for the monitoring and measurement of requirements was not adequately validated.

Specifically,
Your firm's Monitor Program (b) (4) software, used in calibration procedure TM-118 Rev C and quality test procedure (b) (4) for calibration and testing of (b) (4), your part number for (b) (4), foot pedal accessory devices used to control Class IV medical lasers, was not adequately validated.

The validation, TM-117 Rev A, September 26, 2013, is inadequate because it does not include:

1)Raw data from validation testing
2)Pass/fail criteria or results
3)Statistical analysis or sample size rationale
4)Verification that the software accurately measures output values and reliably detects nonconforming devices

In (b) (4): (b) (4) units (MRRs 14522, 15153, 15266, 15338, 15392, 15407, 15613) passed your firm's (b) (4) for calibration but failed customer testing for calibration. Additionally, on 02/06/2026, during the testing setup of Monitor Program (b) (4), there were multiple software COM port errors in both in-process assembly and final product testing areas that were discussed as routine and not investigated.

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OBSERVATION 6

Personnel performing work that affects product quality are not adequately competent based on appropriate.

Specifically,

A) In Job 438651 ((b)(4) units of (b)(4), your part number for (b)(4), foot pedal accessory devices used to control Class IV medical lasers), the assembler skipped Step (b)(4) despite production (b)(4) specifying: Step (b)(4) → Step (b)(4). Your firm described that: "(b)(4) ." The assembler performed rework to re-torque the (b)(4), which resulted in nonconforming product. Training records for this employee do not include the Nonconforming material or production rework/repair request form Q6-12 Rev N, or Nonconforming Material Control procedure Q006 Rev D3.

B) While discussing an employee's training at your firm's Plainfield location with an employee performing (b)(4) operations, the employee stated they had worked for (b)(4) and stated they were not aware of written work instructions. They explained that they had been trained on the job by another employee to learn the (b)(4) operations. This is discrepant with your firm's training record for this employee that states that they were trained on the documented work instructions (MWI 028, MWI 030).

***DATES OF INSPECTION**

2/04/2026(Wed), 2/05/2026(Thu), 2/06/2026(Fri), 2/10/2026(Tue), 2/12/2026(Thu), 2/17/2026(Tue), 2/20/2026(Fri), 2/25/2026(Wed), 3/04/2026(Wed), 3/06/2026(Fri)

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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."