Savaria Concord Lifts, Inc. 8/3/16

Department of Health and Human Services

Public Health Service
Food and Drug Administration
10903 New Hampshire Avenue
White Oak Building 66
Silver Spring, MD 20993

WARNING LETTER
AUG 3, 2016

VIA UNITED PARCEL SERVICE

Marcel Bourassa
President/CEO
Savaria Concord Lifts, Inc.
2 Walker Drive
Brampton, Ontario L6T 5E
Canada

Dear Mr. Bourassa:

During an inspection of your firm located at 2 Walker Drive, Brampton, Ontario, Canada, on February 15, 2016, through February 18, 2016, an investigator from the United States Food and Drug Administration (FDA) determined that your firm manufactures Omega Incline Platform lifts, Multi lifts and wheelchair accessible vans. Under section 201 (h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321(h), these products are devices because they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or to affect the structure or function of the body.

This inspection revealed that these devices are adulterated within the meaning of section 501 (h) of the Act, 21 U.S.C. § 351 (h), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the current good manufacturing practice requirements of the Quality System regulation found at Title 21, Code of Federal Regulations (CFR), Part 820. We received a response from Robert Berthiaume, European Business Vice President dated March 8, 2016 concerning our investigator's observations noted on the Form FDA 483 (FDA 483), List of Inspectional Observations, which was issued to your firm. We address this response below, in relation to each of the noted violations. These violations include, but are not limited to, the following:

1. Failure to establish and maintain procedures for implementing corrective and preventive action, as required by 21 CFR 820.100. For example:

a. Your firm's Corrective and Preventive Action Procedure (QP 09, Rev. 0) does not include requirements for:

i. Analyzing quality data to identify existing and potential causes of nonconforming product or other quality problems, using appropriate statistical methodology where necessary.

ii. Verifying or validating the corrective and preventive action to ensure such action is effective and does not adversely affect the finished device.

iii. Implementing and recording changes in methods and procedures to correct and prevent identified quality problems.

iv. Ensuring that information related to quality problems and nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of such problems.

v. Submitting relevant information on identified quality problems as well as corrective and preventive actions for management review.

b. There was no documentation of the investigation or the corrective and preventive actions for CAPAs QI 445 and QI 578. These CAPAs were closed without verifying or validating the actions to ensure that those actions were effective and did not adversely affect the finished device.

We reviewed your firm's response and conclude that it is not adequate. Your firm's response states that this is a group task procedure to be addressed and implemented by September 2016. However, the response did not include the specific corrections to address the missing elements of 21 CFR 820.100. Your firm also did not perform

retrospective reviews of closed CAPAs and contemporaneous quality data to determine if new CAPAs should be opened, or for closed CAPAs to determine if they were not verified or validated as effective.

2. Failure to adequately establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit, as required by 21 CFR 820.198(a). For example:

a. Your firm's procedure does not include requirements to ensure oral complaints are documented upon receipt.

b. Your firm indicated that not all oral complaints are documented due to human error.

c. Four complaints from your fiscal year 2015 (Tickets# 37671, 37481, 38368 and 38263) reviewed during the inspection did not include an MDR determination.

We reviewed your firm's response and conclude that it is not adequate. Your firm's response did not address revising its complaint procedures to ensure all oral complaints received are documented upon receipt. Further, your firm's response did not address whether your firm plans to retrospectively review complaints to ensure received complaints are evaluated for MDR reportability. Your firm should also address corrective actions and effectiveness verifications taken to address these concerns.

3. Failure to review, evaluate, and investigate complaints involving the possible failure of a device, labeling, or packaging to meet any of its specifications unless such investigation has already been performed for a similar complaint and another investigation is not necessary, as required by 21 CFR 820.198(c). Your firm's complaint handling procedures SAV-T -OP17 and SAV-T -OP16 require quality issues to be reviewed and investigated. However, your firm did not investigate the following complaints:

a. Ticket #37671, dated 10/19/2015, states "client was using unit load bang found a roller split in half' for a multi-lift device. An investigation was not conducted for this quality issue.

b. Ticket #37 481, dated 1 0/21/2015, states "looking for warranty replacement on spring hinges; no tension at both hinges" for a multi-lift device. An investigation was not conducted for this quality issue.

c. Ticket #38368, dated 12/15/2015, states "go up with a load and the top bearing is creating heat and sometimes the lift stops mid-way while motor keeps running; nut is spinning" for a multi-lift device. An investigation was not conducted for this quality

issue.

d. Ticket #38263, dated 12/7/2015, states "dropping door lock too soon; door not relocking; door would only open 2 to 3" and oscillate there" for a multi-lift device. An investigation was not conducted for this quality issue.

We reviewed your firm's response and conclude that it is not adequate. Your firm's response did not address whether your firm plans to retrospectively review complaints to ensure complaints are investigated. Your firm should address corrective actions and effectiveness verifications taken to address these concerns.

4. Failure to ensure that when computers or automated data processing systems are used as part of production or the quality system, the manufacturer shall validate computer software for its intended use according to an established protocol, as required by 21 CFR 820.70(i). For example, your firm's **(b)(4)** software has not been validated for its intended use. This software is used for documentation and tracking of product design and design change projects, as well as for quality related activities such as complaints, corrective and preventive actions and nonconformances.

We reviewed your firm's response and conclude that it is not adequate. Your firm's response indicated that a review of the **(b)(4)** for process and forms, tech support database, **(b)(4)**, and the new **(b)(4)** system will be reviewed for FDA compliance to 21 CFR 11 and 21 CFR 820. However, it does not describe whether unvalidated software systems may have led to errors, and the risks associated with those errors. Your firm should complete and submit the results of the retrospective review, the details of corrective actions planned as a result of the review, and effectiveness verifications.

5. Failure to establish and maintain procedures to control product that does not conform to specified requirements, as required by 21 CFR 820.90(a). For example, your firm's nonconformance procedures SAV-T-OP18 and SAV-T-OP19 state the method for documenting nonconformances is per the nonconformance report (NCR). However, your firm indicated that an NCR was not generated for the following nonconformities observed during final acceptance testing:

a. **(b)(4)**, dated 1/18/2016, states "**(b)(4)**" for a multi-lift device. An NCR was not initiated for this nonconformance.

b. **(b)(4)**, dated 1/26/2016, states "**(b)(4)**" for a multi-lift device. An NCR was not initiated for this nonconformance.

We reviewed your firm's response and conclude that it is not adequate. Your firm's response did not address whether your firm plans to retrospectively review nonconformance files to ensure NCRs were initiated and addressed as appropriate.

Your firm should address corrective actions and effectiveness verifications taken to address these concerns.

6. Failure to establish and maintain procedures that define the responsibility for review and the authority for the disposition of nonconforming product, as required by 21 CFR 820.90(b)(1). For example, your firm's nonconforming procedures SAV-T-OP18 and SAV-T-OP19 do not require documentation of the disposition of nonconforming product. In addition, your firm indicated that the disposition of nonconforming components that were "**(b)(4)**" were not documented.

We reviewed your firm's response and conclude that it is not adequate. Your firm's response did not address revising its nonconforming procedures to ensure that the dispositions of nonconforming products are documented. Further, your firm did not address whether your firm plans to perform a retrospective review to determine if nonconforming products were properly documented, segregated, dispositioned appropriately, and whether corrective actions are required. Your firm should address corrective actions and effectiveness verifications taken to address these concerns.

7. Failure to establish and maintain procedures for rework, to include retesting and reevaluation of the nonconforming product after rework, to ensure that the product meets its current approved specifications, as required by 21 CFR 820.90(b)(2). For example, your firm's nonconforming procedures SAV-T -OP18 and SAV-T -OP19 do not require rework and reevaluation activities and results, including a determination of any adverse effect from the rework upon the product, to be documented in the device history records (DHR). In addition, none of the activities related to rework, retesting and re-evaluation of nonconforming product were documented in the DHR for multi-lift devices, **(b)(4)** after rework was performed.

We reviewed your firm's response and conclude that it is not adequate. Your firm's response did not address revising its nonconforming procedures to ensure rework, re-testing, and re-evaluation activities and results are documented in the DHR. Further, your firm's response did not indicate whether your firm plans to retrospectively review nonconformance files to ensure rework, re-testing, and re-evaluation activities and results are documented in the DHRs. Your firm should address corrective actions and effectiveness verifications taken to address these concerns.

Our inspection (also) revealed that your firm's Wheelchair elevator is misbranded under Section 502(t)(2) of the Act, 21 U.S.C. § 352(t)(2), in that your firm failed or refused to furnish material or information respecting the device that is required by or under section 519 of the Act, 21 U.S.C. § 360i, and 21 CFR Part 803- Medical Device Reporting.

Significant violations include, but are not limited to, the following:

8. Failure to submit a report to FDA no later than 30 calendar days after the day that your firm became aware of information, from any source, that reasonably suggests that a device that it markets had malfunctioned and this device or a similar device that your firm markets would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur, as required by 21 CFR 803.50(a)(2). For example, your firm initiated a Device Field Correction dated February 18, 2014, for a malfunction of your firm's Omega Incline Platform Lift device. Your firm did not justify whether the malfunction referenced in your firm's Device Field Correction notice would not be likely to cause or contribute to a death or serious injury, if it were to recur. Your firm should submit an MDR for the event that triggered the field correction.

9. Failure to adequately develop, maintain and implement written MDR procedures as required by 21 CFR 803.17. For example: Your firm provided an MDR Procedure titled: "Medical Device Reporting Procedure" SAV-T-OP15, Rev. 01, Date of issue 2016-02-01, Effective Date 2016-02-01. After reviewing your firm's MDR procedure the following was noted:

a. SAV-T-OP15, Rev. 01 does not establish internal systems that provide for timely and effective identification, communication, and evaluation of events that may be subject to MDR requirements. For example, there are no definitions of what your firm will consider to be a reportable event under 21 CFR Part 803. The exclusion of definitions from 21 CFR 803.3 for the terms "become aware," "caused or contributed," "malfunction," "MDR reportable event," and "serious injury," and the definition for the term "reasonably suggests,'' found in 803.20(c)(1) may lead your firm to make an incorrect reportability decision when evaluating a complaint that may meet the criteria for reporting under 21 CFR 803.50(a).

b. SAV-T-OP15, Rev. 01 does not establish internal systems that provide for a standardized review process to determine when an event meets the criteria for reporting under this part. For example:

i. There are no instructions for conducting a complete investigation of each event and evaluating the cause of the event.

ii. The procedure, as written does not specify who makes the decision for reporting events to FDA.

iii. There are no instructions for how your firm will evaluate information about an event to make MDR reportability determinations in a timely manner.

10. SAV-T-OP15, Rev. 01 does not establish internal systems that provide for timely transmission of complete medical device reports. Specifically, the following are not addressed:

a. The circumstances under which your firm must submit supplemental or follow-up, 5 day report and the requirements for such reports.

b. The procedure does not include a reference for the submission of MDR reportable events using the mandatory 3500A or electronic equivalent.

c. How your firm will submit all information reasonably known to it for each event. Specifically, which sections of the 3500A will need to be completed to include all information found in the firm's possession and any information that becomes available as a result of a reasonable follow up within its firm.

d. Although the procedure includes references to 30 day reports, it does not specify calendar days and work days, respectively.

11. SAV-T-OP15, Rev. 01 does not describe how your firm will address documentation and record-keeping requirements, including:

a. Documentation of adverse event related information maintained as MDR event files.

b. Information that was evaluated to determine if an event was reportable.

c. Documentation of the deliberations and decision-making processes used to determine if a device-related death, serious injury, or malfunction was or was not reportable.

d. Systems that ensure access to information that facilitates timely follow-up an inspection by FDA.

The adequacy of your firm's response cannot be determined at this time. Although your firm indicates it plans to address the issues for its current MDR procedure within six months, your firm did not provide a revised MDR procedure in its response. Without the documentation in hand we cannot determine the adequacy of your firm's response.

If your firm wishes to discuss the MDR related issues noted above, please contact the Reportability Review Team by email at ReportabilityReviewTeam@fda.hhs.gov

Our inspection also revealed that your firm's Omega Incline Platform Lift device are misbranded under section 502(t)(2) of the Act, 21 U.S. C.§ 352(t)(2), in that your firm failed or refused to furnish material or information respecting the device that is required by or under section 519 of the Act, 21 U.S. C.§ 360i, and 21 CFR Part 806-Medical Device; Reports of Corrections and Removals. Significant violations include, but are not limited to, the following:

12. Failure to submit a Report of Correction or Removal for a medical device correction or removal initiated to reduce a risk to health or to remedy a violation of the Act caused by the device, which may present a risk to health, as required by 21 CFR 806.10. For example, your firm initiated a correction in February, 2014, for the Omega Incline Platform Lift, due to a complaint. The purpose of the correction was to eliminate the possibility of the upper trolley separating from the main carriage. Your firm conducted a correction of these devices; however, no report was filed to FDA within 1 0 working days of initiating this correction.

We reviewed your firm's response and conclude that it is not adequate. Your firm indicates it plans to systematically analyze each customer issue according to the reporting from the Tech Database, in order to report deficiencies or accidents triggered by certain criteria, including risk and fault analysis, within six months. However, your firm did not provide evidence of these corrective actions. Further, your firm has not reported the February, 2014, Omega Incline Platform Lift correction or removal to FDA.

Your firm should update its procedures to follow the requirements under 21 CFR Part 806 Medical Devices; Reports of Corrections and Removals, and the guidance provided by the 21 CFR Part 7 Recall Policy, to ensure that all required information is provided or documented. In addition, your firm should refer to CDRH recall classifications to evaluate future corrections and removals, thereby maintaining consistency in their Health Hazard Evaluations and-compliance with reporting requirements. Further, your firm should conduct health risk assessments following the definition of risk to health in 21 CFR 806.20), to support the reporting decisions for future medical device corrections or removals.

U.S. federal agencies may be advised of the issuance of Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, premarket approval applications for Class Ill devices to which the Quality System regulation deviations are reasonably related will not be approved until the violations have been corrected.

Please notify this office in writing, within fifteen business days from the date you receive this letter, of the specific steps your firm has taken to correct the noted violations, including an explanation of how your firm plans to prevent these violations, or similar violations, from occurring again. Include documentation of the corrections and/or corrective action (which must address systemic problems) that your firm has taken. If your firm's planned corrections and/or corrective actions will occur over time, please include a timetable for implementation of those activities. If corrections and/or corrective actions cannot be completed within fifteen business days, state the reason for the delay and the time within which these activities will be completed. Please provide a translation of documentation not in English to facilitate our review. We will

notify you regarding the adequacy of your firm's response(s) and the need to re-inspect your firm's facility to verify that the appropriate corrections and/or corrective actions have been made.

Your firm's response should be sent to: Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Field Inspections Support Branch, White Oak Building 66, Rm 2622, 10903 New Hampshire Ave., Silver Spring, MD 20993. Refer to CMS case # 498435 when replying. If you have any questions about the contents of this letter, please contact: Daniel Walter, Chief, Foreign Enforcement Branch, at feb@fda.hhs.gov (email) or +1 (240)402-4020 (telephone), or +1(301)847-8138 {fax).

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your firm's facility. It is your firm's responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violations noted in this letter and in the Inspectional Observations, FDA 483, issued at the close of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality management systems. Your firm should investigate and determine the causes of the violations, and take prompt actions to correct the violations and bring the products into compliance.

Sincerely yours,
/S/
CAPT Boyd, MPH, USPHS
Deputy Director for Regulatory Affairs
Office of Compliance
Center for Devices and Radiological Health

cc:
US Agent:
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