

Lordex, Inc.
15915, Katy Freeway
Suite 645
Houston, TX 77094

March 3, 2004

Mr. Thao Ta
Compliance officer
Food and Drug Administration
Department of Health and Human Services, Dallas District
4040 North Central Expressway
Dallas, Texas 75204-3145

Ref: 2004-DAL-WL-09
Subject: Response Update to Warning Letter- 2004-DAL-WL-09

Dear Mr. Ta,

This is a follow up letter to our previous response dated 2/2/04 to your Warning letter 2004-DAL-WL-09.

We are pleased to inform you that we have addressed the issues stated in your Warning letter and taken proper remedial action to correct these issues.

Please find attached herewith, details of the actions taken based on the items stated in the Warning letter. This is to ensure the conformance with regulations applicable to the manufacture of medical devices as defined in sections 210(h) and 501(h) of the Federal Food, Drug and Cosmetic Act and Current Good Manufacturing Practices (cGMP) requirements of the quality System Regulations (QSR) per title 21 and Code of federal regulation (CFR), Part 820.

The table-1 that was included in the initial response dated 2/2//04 which addressed each item from the warning letter and the action taken by Lordex Inc., has now been updated. The changes are highlighted in bold and the corresponding explanation is provided in the comment section.

Additional procedures have been developed and implemented to enhance quality system and meet Quality System Regulation. The operational manual has been updated to include labeling information to comply with the Prescription device regulations 21 CFR 801.109 (Please see Attachment-N).

All the personnel at Lordex Inc have completed QSR/GMP training as of 2/25/04. Please see the attached training record. (Attachment-M)

As stated in the initial response, Lordex will complete the required documentation and implementation by 3/15/04.

This represents a clear portrayal of actions taken and of the new policies that have been implemented to comply with regulations and prevent such occurrences in the future. Lordex Inc. remains committed to abide by the regulations applicable to the manufacturing of medical devices.

Attached herewith, an electronic copy of our responses to the warning letter issued to Dr John Boren, President and CEO of Lordex Inc. on 29th December, 2003. We are requesting that both the responses be posted on your web site with the warning letter in accordance with the guidelines of the pilot program.

Thank you,

Sincerely,

Dr. John P. Boren

President

Lordex, Inc.

February 2, 2004

RESPONSE TO WARNING LETTER 2004-DAL-WL-09

Mr. Thao Ta
Compliance Officer
Food and Drug Administration
Department of Health and Human Services, Dallas District
4040 North Central Expressway
Dallas, Texas 75204-3145

Ref.: 2004-DAL-WL-09

Dear Mr. Ta,

In response to Warning Letter number 2004-DAL-WL-09 (Attachment A) received January 6, 2004, Lordex, Inc. (Lordex) submits this letter of intent to correct cited observations. This Warning Letter Response identifies the specific actions to be taken to address and correct the observations cited. As a matter of record, also please note that Lordex requested a deadline extension to the response to the Warning Letter (Attachment B)

Following our inspection of October 2003, and subsequent receipt of Form FDA-483 (Attachment C), a written response (Attachment D) was sent on November 6, 2003 reflecting Lordex, Inc.'s commitment to quality and regulatory compliance. In it, Lordex states the intent to apply the resources required to meet and exceed the expectations of FDA.

Lordex recognizes the requirement to comply with regulations applicable to the manufacture of medical devices as defined in Sections 201(h) and 501(h) of the Federal Food, Drug, and Cosmetic Act, and Current Good Manufacturing Practice (cGMP) requirements of the Quality System Regulations (QSR) per Title 21, Code of Federal Regulation (CFR), Part 820. It is the intent of Lordex to address each observation, and commit to actions to be taken to resolve them within a specified timeframe. To date, Lordex has retained a qualified consulting firm to expedite the implementation of a Quality System, and document a compliant state of control at Lordex, Inc.

Each Warning Letter Item (WLI) is addressed individually with a description of actions to be taken. Table I (Attachment E) includes specific policies, procedures, and supporting documentation to be written and approved with projected timeframes for implementation.

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Warning Letter Item 1. (WLI-1)

Lordex, Inc. has initiated the development of a Quality System per 21 CFR 820.20. This system will be implemented through the culmination of all applicable policies and procedures required to define, describe, and implement the standards and behaviors that ensure regulatory compliance and product quality. Many of the responses to the remaining Warning Letter Items directly contribute to this goal. As WLI-1 is an overall observation as to executive responsibility to implement a Quality System, specific descriptions of each component of the Quality System are reflected in the responses that follow. However, the foundation of the Quality System at Lordex, Inc. is the Quality Manual that will include but not be limited to:

- An executive statement of commitment to produce quality products that perform as purported or Quality Policy, (Attachment F).
- A description of all products produced and their intended purpose.
- An organization chart, which clearly defines Quality Control person at Lordex, Inc. (Attachment G).
- Designated review and authorization of critical documents.
- A Quality Plan that delineates the quality environment at Lordex, Inc.
- A compliance matrix (Attachment H) identifying the policies and procedures in place to support the Quality Plan and comply with specific requirements in CFR 21, Part 820. This matrix is consistent with the requirements for a Quality System Record per 21 CFR, 820.186.

As Lordex, Inc. is a very small firm (██████ employees including the President), the Quality Manual will also be the repository for company policies including those designed and implemented to support product quality. The previously mentioned compliance matrix will clearly identify which Standard Operating Procedures (SOP) are in place to implement the commitments in the Quality Manual. The remaining responses address the specific concerns cited in WLI-1 as well as others cited on Form FDA-483. See WLI-1 in Table I.

Warning Letter Item 2. (WLI-2)

Lordex, Inc. recognizes the importance of the control of suppliers that contribute components to the products. A comprehensive supplier certification program is being established to ensure that the components received will conform to quality requirements. This will include objective evaluation of the supplier's operations as it pertains to Lordex products with an emphasis on communication of adherence to set standards. Lordex, Inc. will document and communicate quality expectations to the suppliers, and insist, as part of the certification process, that applicable purchasing agreements include the requirement to notify Lordex of any changes to the components.

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In addition, Lordex intends to identify what constitutes a critical component as it applies to the Rx-1 Lumbar Extension Machine and the Lordex Decompression Unit. These will be the focus of the certification process. Documentation of rejected incoming material will be documented and used for future supplier evaluations. (See WLI-3) See WLI-2 in Table I for procedure projection.

Warning Letter Item 3. (WLI-3)

Procedures to control the receipt and acceptance of incoming products and materials are being established per 21 CFR 820.80 (b). A documented process of examination and approval of critical components is also being established to include physical isolation of received goods from assembly area until examination verifies the products are consistent with design specifications and are in proper working order. In the case of the Dynatron 900 Traction System, acceptance will depend upon verification of operating condition, and a bench test of the traction device at specified weight.

Documentation of accepted critical components will include an acceptance tag that will remain with the component until assembly, then removed and included in the Device History Record (DHR) for traceability. Rejected critical components will be returned to the supplier and noted in the component history file for use in future supplier evaluations (See WLI-2 and WLI-5). Refer to WLI-3 in Table I.

Warning Letter Item 4. (WLI-4)

Consistent with cGMP QSR requirements, Lordex Inc will employ a stratified documentation system that will include policies, SOPs, and detailed work instructions. A designated SOP will control the initiation, development, review, and approval of all documents responsible for maintaining a state of control within the Quality System. This will include detailed instructions for the assembly and testing of both the LDU and RX-1 machines. This will constitute release activities, and will be documented as such in the DHR.

Furthermore, this designated SOP that controls procedure/documentation management will also establish and implement the change control of all critical documentation including but not limited to:

- Device Master Record (DMR)
- Device History File (DHF)
- Design Changes
- Audit Forms and Schedules
- Checklists or Forms
- Controlled Parts Lists (Fasteners, etc.)

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This SOP will also define and control effective date assignment, purge and replacement procedures, and archiving. In addition to WLI-4, this is in response to FDA Form-483 Observation 1, Houston, and FDA Form-483 Observation 11, Brookshire. Refer to WLI-4 in Table I.

In addition, an SOP, closely related and dependent to the one described in above, is being developed to implement a Corrective Action Preventive Action (CAPA) program. The goal of this procedure will be to delineate the rationale and process by which Lordex, Inc. will conduct investigations of events that are subject to Medical Device Reporting regulations (MDR) (See FDA Form-483, Observations 2 and 12)

Lordex, Inc. recognizes the criticality of sound investigation practices, and will include this commitment in the Quality Manual as well this SOP for practical application. CAPA activities will include, but are not limited to:

- Investigation practices
- Root cause analysis
- Corrective action
- Remedial steps required to prevent recurrence
- Documentation
- Trending

Warning Letter Item 5. (WLI-5)

As stated in the response to WLI-3, a controlled procedure has been developed to process non-conforming products when received, evaluated, and rejected. The non-conforming product will be isolated and returned to the supplier with due documentation included in the component history file for traceability and future use in supplier evaluations. See WLI-5 in Table I.

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Warning Letter Item 6. (WLI-6)

Establishment and control of Device History Records (DHR) is of paramount priority for Lordex, Inc. Lordex recognizes that each unit produced requires a history of its components, assembly, testing, and release to comply with regulations for medical devices. A separate and focused SOP has been developed to describe the DHR process. This SOP, (and all others), are being tied into the policies found in the Quality Manual and specifically into the Quality Plan therein. The DHR SOP establishes a living production packet that will contain as a minimum, but not limited to:

- Labeling of unique identifying serial number.
- Accept/reject documentation of incoming products and materials.
- Documentation of in-process anomalies during assembly.
- Date of completion of assembly.
- Final inspection/testing documentation.
- Verification the unit was produced in accordance to the DMR.
- Date of release/shipping.
- Customer name and contact information.

The completed DHR is a permanent record of the production of the unit and is filed and controlled per the SOP, Retention and Retrievability of Executed Assembly Records and QSR Document Storage Guidelines. (Refer to WLI-4) See WLI-6 in Table I.

Warning Letter Item 7. (WLI-7)

More developed procedural controls are required to handle customer complaints. A designated SOP is being established to provide compliant direction in the event of a customer complaint. This will include sufficient trending over time to deduce possible common defects or opportunity for improvement. Working with the DHR program, customer complaints can be used to identify specific problems to prevent recurrence. Customer complaints will be tracked and trended, and reviewed annually for recurring issues. If any trends in complaints warrant a market recall, the designated SOP will ensure withdrawal of affected units is performed in an efficient and compliant manner. See WLI-7 in Table I.

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Warning Letter Item 8. (WLI-8)

Lordex, Inc. recognizes the need for general design/configuration control including all of the elements cited in WLI-8. The vast majority of this control, especially our philosophy/practice of design changes that require appropriate review, risk analysis, and the awareness of impact to current manufacturing, will be reflected in the Quality Plan section of the Quality Manual. By choosing this location, Lordex, Inc. will strive to emphasize the critical impact that design control has on the overall integrity of our products. Subsequent procedures will be developed to ensure practical transfer of design changes including validation and retention of design history files. Management of all changes to any critical documentation at Lordex, Inc. will subject to the standards reflected in the Quality Manual, and processed per the requirements delineated in the Change Control SOP.

Registration of Lordex, Inc. facilities (Attachment X) and listing of products (Attachment Y) with FDA is currently in process and will be submitted prior to your receipt of this response.

Additionally, personnel at Lordex will receive QSR/GMP training within 30 days.

In conclusion, Lordex, Inc. is committed to meeting and exceeding the expectations of the FDA as they are reflected in the Warning Letter 2004-DAL-WL-09 and preceding form 483 items. This response is intended to demonstrate that commitment, and to serve as a working tool to achieve our required level of compliance.

Mr. Ta, if you require any additional information or clarification, please don't hesitate to contact me directly.

Respectfully submitted,

Dr. John P. Boren
President