



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
a11165d

December 29, 2003

Dallas District
4040 North Central Expressway
Dallas, Texas 75204-3145

Ref: 2004-DAL-WL-09

WARNING LETTER

CERTIFIED MAIL
RETURNED RECEIPT REQUESTED

Dr. John P. Boren, D.C., and President
Lordex, Inc.
15915 Katy Freeway, Suite 645
Houston, Texas 77094

Dear Dr. Boren:

Our review of information collected during an inspection of your firm's operations located at the above-referenced address and 3723 10th Street, Brookshire, Texas 77423 on October 15 through November 15, 2003, revealed that your firm manufactures the RX-1 Lumbar Extension Machine and the Lordex Decompression Unit (LDU), which are physical medicine devices intended for treating patients with lower back pain. These products are devices as defined in Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for their manufacturing, packing, storage, or installation are not in conformance with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System Regulations for medical devices, as specified in Title 21, Code of Federal Regulation (CFR), Part 820. At the close of the inspection at each of the two facilities listed above, you were issued a Form FDA-483 which delineated a number of significant GMP inspectional observations which include, but are not limited to, the following:

1. Failure of management with executive responsibility to ensure that an adequate and effective quality system has been fully implemented and maintained at all levels of the organization [21 CFR 820.20]. For example, your firm has not established (a) a quality policy, a quality plan, procedures for management review and internal audit, device history records, and complaint files; and (b) procedures for quality and specification requirements that must be met by contractors, acceptance and rejection of finished devices, packaging and labeling activities, and complaint handling; and (c) design

control procedures and design history records. See FDA-483 Items 1 through 3 issued to you at your corporate office in Houston, Texas; and FDA-483 Items 1 through 12 issued to you at your manufacturing facility in Brookshire, Texas.

2. Failure to establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements, including quality requirements [21 CFR 820.50] [FDA-483 Item 4, Brookshire, Texas]. For example, your firm (a) has not specified and documented quality requirements that must be met by the component suppliers; (b) has not documented your evaluation of the component suppliers for their ability to meet your quality requirements; and (c) has not maintained purchasing documents that include an agreement with the component suppliers to notify your firm of any changes in the product or services.
3. Failure to establish and maintain procedures for acceptance of incoming product [21 CFR 820.80(b)] [FDA-483 Item 5, Brookshire, Texas]. For example, your firm has no written procedures for inspecting, testing, or verifying the incoming [REDACTED] Traction Systems and fabricated/machined parts and for documenting the results of your acceptance or rejection.
4. Failure to establish and maintain process control procedures to include documented instructions, standard operating procedures (SOPs), and methods that define and control the manner of production [21 CFR 820.70(a)(1)] [FDA-483 Item 9, Brookshire, Texas]. For example, your firm has not established written assembly and testing procedures for the LDU and RX-1 machines.
5. Failure to establish and maintain procedures to control product that does not conform to specified requirements, including the identification, documentation, segregation, disposition, and investigation of nonconforming products [21 CFR 820.90(a)] [FDA-483 Item 6, Brookshire, Texas]. For example, your firm has not kept records of your evaluation and disposition of nonconforming [REDACTED] Blocks, which had partially or completely missing drill holes.
6. Failure to establish and maintain procedures to ensure that device history records for each batch, lot, or unit are maintained to demonstrate that the device is manufactured in accordance with the device master record [21 CFR 820.184] [FDA-483 Item 8, Brookshire, Texas]. For example, your firm has no device history records in order to document device assembly acceptance results, device labeling and serial numbers, and dates of manufacture.
7. Failure to maintain complaint files and failure to establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally

designated unit [21 CFR 820.198(a)] [FDA-483 Item 3, Brookshire, Texas]. For example, your firm (a) has not established written complaint handling procedures to indicate how complaints are investigated, documented, and handled by both the corporate site and the manufacturing site; and (b) has not maintained complaint files.

8. Failure to establish and maintain procedures to control the design of the devices to ensure that specified design requirements are met [21 CFR 820.30] [FDA-483 Items 1 through 3, Houston, Texas]. For example, your firm has not established procedures and documentation to include design plans, design inputs, design outputs, design reviews, design verification and validation, design risk analysis, design transfer, design changes, and design history files for the LDU and RX-1 machines.

Our inspection also documented that you have not registered either of your facilities (design control site and manufacturing site) as a medical device manufacturer and listed the devices with the FDA to ensure compliance with 21 CFR 807. Failure to register a firm's facilities and list its devices with FDA constitutes misbranding under Section 502(o) of the Act. You can obtain the registration and listing form from our website at <http://www.fda.gov>.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and the regulations. The specific violations noted in this letter and in the Form FDA-483 issued at the close of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems.

You are responsible for investigating and determining the causes of the violations identified by the FDA. You also must promptly initiate permanent corrective actions and preventative action on your quality system.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

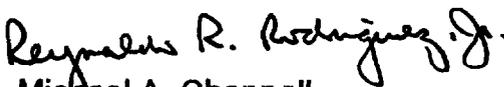
Should you need general information about FDA's requirements for medical device manufacturers, you may obtain information on the FDA's website at <http://www.fda.gov> or by contacting our Division of Small Manufacturers, International and Consumer Assistance (DSMICA) at (800) 638-2041.

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Lordex, Incorporated
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Please provide this office in writing within 15 working days of receipt of this letter a report of the specific steps you have taken, or will take to identify and correct any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed.

Your reply should be directed to Thao Ta, Compliance Officer, at the above letterhead address. If you have any questions concerning this matter, you may contact Mr. Ta at (214) 253-5217.

Sincerely,


for Michael A. Chappell
Dallas District Director

MAC:txt