



WARNING LETTER

November 25, 2003

Certified Mail
Return Receipt Requested

W/L 10-04

Richard K. Gerlach
President and C.E.O.
Clinical Laser Systems, Inc.
22750 Hawthorne Boulevard
Torrance, CA 90505

Dear Mr. Gerlach:

During an inspection of your medical device firm located in Torrance, California, conducted from September 22 to October 2, 2003, our investigator determined that your firm manufactures laser film digitizers which are intended to scan x-rays and transmit the resulting images to host computers for review and archiving for medical purposes. The digitizers are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321(h).

Our inspection disclosed that your 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, manufacturing, packing, storage, and installation are not in conformity with the current Good Manufacturing Practice (cGMP) requirements set forth in the Quality System (QS) Regulation, codified in Title 21, Code of Federal Regulations (CFR), Part 820. The inspector noted the following QS Regulation violations, which are also listed in the form FDA 483 provided to your facility at the end of the inspection:

1. Failure to establish and maintain a quality system that is appropriate for the specific device(s) designed or manufactured, and that meets the requirements of the QS Regulation [21 CFR 820.5]. Specifically:
 - Management with executive responsibility has not established its policy and objectives for, and commitment to, quality, as required by 21 CFR 820.20(a).
 - Management with executive responsibility has not ensured that the quality policy is understood, implemented, and maintained at all levels of the organization, as required by 21 CFR 820.20(a).

- You have not provided adequate resources, including the assignment of trained personnel, for management, performance of work, and assessment activities, including internal quality audits, to meet the requirements of the QS Regulation, as required by 21 CFR 820.20(b)(2).
 - You have not established quality system procedures and instructions, as required by 21 CFR 820.20(e).
 - Management with executive responsibility has not appointed or documented the appointment of a member of management who, irrespective of other responsibilities, has established authority over and responsibility for (1) ensuring that quality system requirements are effectively established and effectively maintained in accordance with the QS Regulation and (2) reporting on the performance of the quality system to management with executive responsibility for review, as required by 21 CFR 820.20(b)(3).
 - Management with executive responsibility has not reviewed the suitability and effectiveness of the quality system at defined intervals and with sufficient frequency according to established procedures to ensure that the quality system satisfies the requirements of the QS Regulation and the manufacturer's established quality policy and objectives, as required by 21 CFR 820.20(c).
2. Failure to establish procedures for quality audits and to conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system [21 CFR 820.22].
 3. Failure to establish and maintain procedures for implementing corrective and preventive action, including requirements for analyzing sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems [21 CFR 820.100(a)(1)].
 4. Failure to establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit to ensure that all complaints are processed in a uniform and timely manner and that complaints are evaluated to determine whether the complaint represents an event that is required to be reported to FDA under 21 CFR part 803 or 804, Medical Device Reporting [21 CFR 820.198].
 5. Failure to establish and maintain procedures to control the design of the device to ensure that specified design requirements are met [21 CFR 820.30(a)(1)].
 6. Failure to establish and maintain procedures to control all documents that are required by the QS Regulation; to designate an individual(s) to review for adequacy and approve prior to issuance all documents established to meet the requirements of the QS Regulation or when changes have been made to the

documents; and to have changes to documents reviewed and approved by an individual(s) in the same function or organization that performed the original review and approval, unless specifically designated otherwise [21 CFR 820.40].

7. Failure to establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements [21 CFR 820.50].
8. Failure to document process validation activities and results [21 CFR 820.75].
9. Failure to establish and maintain procedures to control product that does not conform to specified requirements, including procedures addressing the identification, documentation, evaluation, segregation and disposition of nonconforming product, as required by 21 CFR 820.90.

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 applicable requirement of the Act and FDA implementing regulations. The specific violations noted in this letter and in the form FDA 483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance system. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

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. Additionally, no pre-market submissions for devices to which the GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates For Exportability will be approved until the violations related to the subject devices have been corrected.

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

Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you to correct the noted violations, including an explanation of each step being taken to identify and make corrections to 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 within which the corrections will be completed.

We acknowledge receipt of your written response dated November 16, 2003 addressing the observations listed on the form FDA 483 issued to you on October 2, 2003. We have completed our review of your response and have determined that your response does not

Mr. Richard K. Gerlach, Clinical Laser Systems, Inc.

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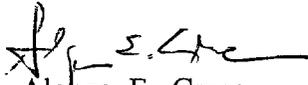
adequately address our concerns. Your response does not contain sufficient documentation of the activities conducted by your firm to correct the deficiencies disclosed during our inspection. Additionally, your proposal to implement corrective action within 6 to 9 months is not acceptable.

If you have any questions relating to this letter, please contact Senior Compliance Officer, Dannie E. Rowland at (949) 608-4461.

Please submit your response to:

Acting Director, Compliance Branch
Food and Drug Administration
19701 Fairchild
Irvine, CA 92612-2445

Sincerely,



Aloha E. Cruse
District Director
Los Angeles District Office

Cc: Richard Gerlach
President
eRadlink, Inc.,
22750 Hawthorne Blvd.
Torrance, CA 90505

Cc: State Department of Public Health
Environmental Health Services
Attn: Chief, Food and Drug Branch
601 North 7th Street, MS-35
Sacramento, CA 94234-7320