DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Cincinnati District Office
Central Region
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Cincinnati, OH 45237-3097
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November 21, 2006

WARNING LETTER
CIN-06-31049-05

VIA FEDERAL EXPRESS

Chun B. Lim
President and CEO
Trionix Research Laboratory, Inc.
8037 Bavaria Road
Twinsburg, OH 44087

Dear Mr. Lim:

During an inspection of your firm located in Twinsburg, OH on July 25 through August 9, 2006, an investigator from the United States Food and Drug Administration (FDA) determined that your firm manufactures nuclear imaging devices. 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 are intended 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 manufacturing, packing, storage, or installation are not in conformity with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation found at Title 21, Code of Federal Regulations (C.F.R.), Part 820. These violations include, but are not limited to, the following:

1) Failure to establish procedures for, and to implement, a corrective and preventive action to prevent the recurrence of nonconforming product. [21 CFR 820.100(a)]

   Specifically, your firm received a complaint on April 22, 2002 that the detector head on the Biad nuclear imaging system fell and trapped a patient. You determined that this failure was caused by the shaft of the ball screw breaking. You also determined that the shaft broke because of system age and metal fatigue. Your firm developed a retrofit which included a new "acme" screw to prevent the detector head from dropping if a similar situation occurs. The retrofit also included a gear and belt change, which makes the motion speed of the device slower. A memo, dated May 22, 2002, to "All Field Service Engineers" stated that your firm would notify all

customers of this retrofit and that retrofits would begin in July of 2002. The retrofit to these devices has not been performed and there is no justification as to why this corrective action has not been implemented.

You informed the investigator during the inspection that you will conduct a recall of all Biad Systems which are still in use. You stated that this retrofit will not occur until January of 2007, so your firm can develop test procedures, assure this corrective action has been validated, and train all the Field Service Engineers. Please update us on the status of this corrective action.

2) Failure to implement procedures for receiving, reviewing, and evaluating complaints; to maintain complaint files; and to review and evaluate complaints to determine if an investigation is necessary. [21 CFR 820.198(a),(b), and (c)]

Specifically, your complaint procedure (T002013- Rev B) has not been used since your former Quality Assurance Manager left your company over five years ago, and no person has been designated to handle complaints. Additionally, oral complaints are recorded on paper, and this paper is discarded after service is dispatched. Furthermore, service reports are not reviewed to determine if the service constitutes a complaint.

3) Failure to assure that the nuclear imaging device met all final acceptance and in-process acceptance criteria and to authorize the release of the device by the signature of a designated individual prior to distribution. [21 CFR 820.80(c)(d)]

Specifically:

- The Device History Record for the Triad XLT nuclear imaging system, serial #231, revealed that over 30 checks/tests, that are required to be performed, were not documented as being completed.

- The Device History Record for the Triad XLT nuclear imaging system, serial #231, also revealed that during in-process testing, several voltage readings, and the hard limit switch's readings were not within specifications. There is no documented acceptance of these deviations.

4) Failure to ensure that equipment is routinely calibrated and inspected. [21 CFR 820.72(a)]

Specifically, the FDA investigator found that all testing/measuring equipment used to manufacture and test components and finished devices that the investigator reviewed had expired calibration. A total of three oscilloscopes, two multimeters, a Ground and Dielectric tester, and 65 different hand crimping tools had expired calibration.

5) Failure to control products that do not conform to specifications. [820.90(a)]

Specifically, the FDA investigator found materials that have been obsoleted, scrapped or found to be nonconforming scattered throughout your facility without being properly identified or

segregated. Additionally, returned units that may be refurbished are not clearly identified. Furthermore, the disposition of these products is not documented.

6) Failure to use the design process for the design changes made to the Biad nuclear imaging system and failure to have written design change control procedures. [21 CFR 820.30(i)]

   Specifically, the design change (retrofit) your firm made to the Biad nuclear imaging system as a result of a complaint that the detector head on the Biad nuclear imaging system fell and trapped a patient (See item #1 above) was not performed using design controls. There is no formal approval of the change, no risk assessment was documented, and there is no verification/ validation protocol.

7) Failure of management with executive responsibility to assure that an adequate and effective quality system has been fully implemented and maintained at all levels of the organization. [21 CFR 820.20]

   Specifically, your firm is not conducting internal quality audits, performing management reviews, capturing/managing complaints, generating corrective/preventive actions, and has not had a person manage the quality system since 1998.

Our inspection also revealed that your Biad Nuclear Imaging devices are misbranded within the meaning of section 502(t)(2) of the Act, 21 U.S.C. 352(t)(2), in that your firm failed to 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 C.F.R. Part 806 – Reports of Corrections and Removals regulation. Significant deviations include, but are not limited to, the following:

- Failure to submit a written report to FDA regarding the correction that your firm made to the detector head of the Biad Nuclear Imaging devices, as required by 21 C.F.R. Part 806.10. This correction was initiated to remedy a violation of the Act caused by the device which may present a risk to health posed by the device. On May 13 and 14, 2002, your firm retrofitted the detector head of the Biad Nuclear Imaging System with acme screws and changed the gear and belt to prevent the detector head from dropping.

FDA regulations require manufacturers and importers to submit a written report to FDA of any correction or removal of a device if the correction or removal was initiated to reduce a risk to health posed by the device. See 21 CFR 806.10 (a)(1). This report must be submitted to FDA within 10 working days of initiating the correction or removal. See 21 C.F.R 806.10(b). Because your actions described above meet the definition of a "correction" in 21 CFR 806.2(d) and because they were initiated to reduce a risk to health, your failure to report them until the issue was raised by our investigator violated 21 CFR 806.10(a)(1).

You should take prompt action to correct the violations addressed in this letter. 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 money penalties. Also, 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

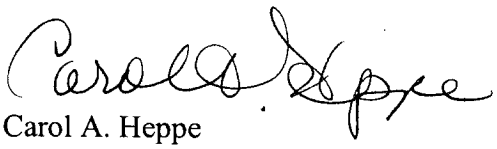
contracts. Additionally, premarket applications for Class III devices to which the Quality System regulation deficiencies are reasonably related will not be approved until the violations have been corrected. Requests for Certificates to Foreign Governments will not be granted until the violations related to the subject devices have been corrected.

Please notify this office within fifteen (15) working days from the date you receive this letter of the specific steps you have taken to correct these noted violations, including an explanation of how you plan to prevent these violations, or similar violations, from occurring again. Include documentation for the corrective actions you have taken. If your planned corrections will occur over time, please include a timetable for implementation of those corrections. 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.

Your response should be sent to Ms. Gina Brackett, Compliance Officer, Food and Drug Administration 6751 Steger Drive, Cincinnati, Ohio 45237. If you have any questions concerning the contents of this letter, you may contact Ms. Brackett at (513) 679-2700, ext. 167, or you may forward a facsimile to her at (513) 679-2773.

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

Sincerely,



Carol A. Heppe
District Director
Cincinnati District