



U.S. FOOD AND DRUG ADMINISTRATION

NEW YORK DISTRICT
850 THIRD AVENUE, BROOKLYN, NEW YORK 11232

5201

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August 12, 1997

WARNING LETTER

Certified Mail Return Receipt Requested

Mr. George N. Zacharopoulos, President
Aktina Medical Physics Corp.
360 North Route 9W
Congers, New York 10920

Re: 69-NYK-97

Dear Mr. Zacharopoulos:

During an inspection of your firm located in Congers, New York, on July 16 thru 25, 1997 our investigator determined that your firm contract manufactures Electron Beam Trays, Tennis Racquet Inserts for Linear Acceleration, Tungsten DOT Reticules and Port Film Gradicules for Siemens Medical Systems, located at 4040 Nelson Avenue, Concord, California 94520. These products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection also 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 manufacturing, packing, storage or installations are not in conformance with the Current Good Manufacturing Practice (GMP) as specified in Title 21, Code of Federal Regulations, (CFR), Part 820, Quality System Regulation, as follows:

1. Failure to establish and maintain procedures for finished device acceptance to ensure that each finished device meets acceptance criteria. Specifically, the documentation of final inspections for the Tennis Racquet Inserts for Linear Acceleration, Tungsten DOT Reticules and Port Film Gradicules were not maintained.

2. Failure to establish and maintain acceptance procedures to ensure that in-process product is controlled, until the required inspection and tests to other verification activities have been completed, or necessary approvals are received and are documented. Specifically, there are no written procedures describing the method of performing final inspections on the Tennis Racquet Inserts for Linear Acceleration, Tungsten DOT Reticules and Port Film Gradicules and Electron Beam Trays. In addition, there are no written procedures for change controls.
3. Failure to maintain complete device history records for the Electron Beam Trays. Specifically,
 - a) The inspection data sheet lot#970408-55, P/N 19946495 did not include an inspection of the digital plugs to ensure that the plugs were properly assembled with the correct resistors, properly labeled with the correct identifying number and conforms to the dimensions outlined on the engineering drawing for trays.
 - b) The inspection data sheet lot#970416-10, P/N 1950604B does not include an inspection of the handle and the perforated holes on the tray to ensure that the device meets the specifications as per the engineering drawing.
 - c) The inspection data sheet lot#970416-0, P/N 1950604B did not include an inspection of the perforated holes on the trays to ensure that the device meets the specifications as per the engineering drawing.
4. Failure to establish procedures for quality audits and conduct 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. Specifically, production records are not reviewed by management having responsibility for the matters audited and internal audits are not being conducted according to your Standard Operating Procedures.
5. Failure to have established procedures for identifying training needs and ensure that all personnel are trained to adequately perform their assigned responsibilities.

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 regulations. The specific violations noted in this letter and in the FDA-483 issued at the closeout 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. If causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

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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 pending applications for premarket approval (PMA's) or export approval requests will be approved and no Premarket notifications [Section 510(k)'s] will be found to be substantially equivalent for products manufactured at the facility in which the above GMP violations were found until the violations 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 the Food and Drug Administration 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 have taken to correct the noted violations. Include 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.

Your reply should be directed to the Food and Drug Administration, 850 Third Avenue, Brooklyn, New York 11232, attention: Anita Fenty, Compliance Officer.

Very truly yours,


Brenda Holman
District Director

cc: President
Siemens Medical Systems
4040 Nelson Avenue
Concord, California 94520