



DEPARTMENT OF HEALTH AND HUMAN SERVICE

Southwest Region

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Food and Drug Administration
Denver District Office
Bldg. 20-Denver Federal Center
P.O. Box 25087
6th Avenue & Kipling Street
Denver, Colorado 80225-0087
Telephone: 303-236-3000
FAX: 303-236-3100

July 19, 2001

WARNING LETTER

CERTIFIED MAIL RETURN RECEIPT REQUESTED

Louis T. Ruggiero, President and CEO
Titan Scan Technologies
9020 Activity Road, Suite D
San Diego, California 92196

Ref # DEN-01-42

Dear Mr. Ruggiero:

The Food & Drug Administration (FDA) conducted an inspection of your firm located at 6750 East 46th Avenue Drive, Suite 100, Denver, Colorado 80216, on February 27, 28, March 1, and March 5, 2001. At that time, Consumer Safety Officer Lori A. Lahmann determined you operate a medical device contract sterilization facility using electron beam technology. Processing of these products, which are considered devices within the meaning of Section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act), cause your facility to be under the jurisdiction of the FDA. A copy of the FD-483, List of Observations, is attached for your ready reference. We regret the delay in issuing this letter to you.

The above inspection revealed that the devices processed by your firm 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 the manufacture, packing, storage, or installation of these devices are not in conformity with the Quality System Regulation (QSR), as specified in Title 21, Code of Federal Regulations, Part 820 (21 CFR 820), as follows:

- Failure to establish and maintain an adequate quality system that is appropriate for the specific medical devices designed and manufactured by your firm, as required by 21 CFR 820.5.
- Failure to provide adequate resources, including the assignment of trained personnel for assessment activities, to meet the requirements of the QSR, as

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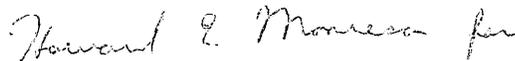
- Failure to establish and maintain procedures for rework, to include retesting and reevaluation of the nonconforming product after rework, to ensure the product meets its current approved specifications, as required by 21 CFR 820.90(b)(2). For example, a (X X X X) lot was underdosed. The product was augmented to bring the minimum dose close to above the targeted range, however, there are no procedures for performing this rework.

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 the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

You should take prompt action to correct these and any other manufacturing or quality systems deviations identified by your internal audits. Failure to promptly correct these deviations may be identified in a follow-up inspection, and 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 days of receipt of this letter, of the additional steps you will be taking to achieve compliance which have not been previously reported to us. Your reply should be sent to the Food and Drug Administration, Denver District Office, Attention: Shelly L. Maifarth, Compliance Officer, at the above address. You may contact her at (303) 236-3046 if you have any questions about this letter.

Sincerely,



Thomas A. Allison
District Director

Attachment:
As Stated

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