



January 5, 2000

Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

WARNING LETTER
CHI-7-00

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ben Z. Reznik, President
Reznik Instrument, Inc.
7337 N. Lawndale Ave.
Skokie, IL 60076

Dear Mr. Reznik:

During an inspection of your establishment located in Skokie, IL, on December 8, 1999, our investigator, Tamara Brey, determined that your establishment manufactures trocars and other surgical instruments. Trocars are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

This 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 manufacturing, packing, storage, or installation are not in conformance with the Quality System/Good Manufacturing Practice (QS/GMP) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to maintain complete Device History Records. For example, Device Master Records lacked a complete date of manufacture, acceptance testing and release records, and the primary identification labeling used for each production unit.
2. Failure to establish procedures to ensure mix-ups, damage, deterioration, contamination, or other adverse effects to product do not occur during handling. For example, your firm did not identify, in the manufacturing area, the acceptance status of raw material, components, and finished devices.
3. Failure to establish procedures for the control of product storage areas to prevent mix-ups, damage, deterioration, contamination, or other adverse effects pending use or distribution and to ensure that no obsolete, rejected, or deteriorated product is used or distributed. For example, your firm did not identify, in the storage area, the acceptance status of raw material, components, and finished devices.
4. Failure to conduct periodic quality audits to ensure the quality system is in compliance with the establish quality system requirements and to determine its effectiveness. For example, your firm has no audit procedures and has not conducted an internal audit.

5. Failure to establish procedures that ensure that complaints are evaluated to determine whether the complaint represents an event that is required to be reported under the Medical Device Reporting regulations.

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 Form 483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your establishment'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.

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 premarket submissions for Class III devices to which the QS/GMP deficiencies are reasonably related will be cleared or approved until the violations have been corrected. Also, no requests for Certificates to Foreign Governments 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 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, 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.

Your response should be sent to Michael Lang, Compliance Officer.

Sincerely,

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Raymond V. Mlecko
District Director