



CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Food and Drug Administration
7200 Lake Ellenor Drive
Orlando, FL 32809

WARNING LETTER

FLA-97-22

February 10, 1997

Esperanto J. Simicich, President
Tico Medical Instruments, Inc.
3600 SR 520
Cocoa, Florida 32926

Dear Mr. Simicich:

During an inspection of your firm located at 3600 State Road 520 Cocoa, Florida on January 6, 8-10, 1997, FDA Investigator R. Kevin Vogel determined that you manufacture Retrograde Infusion Sets (RIS) which are devices as defined by Section 201 (h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The inspection revealed that the 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 the manufacture, packing, storage, or installation are not in conformance with the Current Good Manufacturing Practice (CGMP) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820. These violations include, but are not limited to the following:

- 1) Lack of appropriate corrective action concerning complaints referencing RIS leaking at the stem area.
- 2) Lack of minimum requirement for personnel qualification for personnel completing bonding operations and measurement of stems.
- 3) Lack of sterilization revalidation since 1991 and those that were completed did not include validation protocol or documentation of heat distribution studies done with full loads, or to assure aeration time of ~~(seven)~~ days is adequate to reduce EtO residues to consistently meet specifications.
- 4) Failure to establish, implement and document a Quality Assurance Audit procedure and no Q.A. audit has been completed since 1992.

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- 5) No positive control was used to assure growth of each lot of biological indicators since sterilization validation in 1987.
- 6) Lack of bioburden testing schedule and bioburden testing has not been done since 1989.
- 7) Failure to document some complaints, failure investigations, and conclusions.

This letter is not intended to be 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.

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 awards of contracts. Additionally, no premarket submissions for devices to which GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates for Products for Export 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 fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including (1) each step that has or will be taken to correct the current violations, (2) the timeframe within which the corrections will be completed, (3) the person responsible for effecting correction, and (4) any documentation indicating correction has been achieved and 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.

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Your response should be sent to Timothy J. Couzins, Compliance Officer, Food and Drug Administration, 7200 Lake Ellenor Drive, Suite 120, Orlando, Florida 32809, telephone (407) 648-6913, ext. #264.

Sincerely,



Douglas D. Tolen
Director
Florida District