

DEPARTMENT OF HEALTH & HUMAN SERVICES

HFI
PUBLIC HEALTH SERVICE
M21881



Food and Drug Administration
Denver District Office
Building 20 - Denver Federal Center
P. O. Box 25087
Denver, Colorado 80225
TELEPHONE: 303-236-3000

March 24, 1999

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Dennis R. Scanlan III
President
Sontec Instruments, Inc.
7248 S. Tucson Way
Englewood, CO 80112

Ref # : DEN-99-06

Dear Mr. Scanlan:

During an inspection of your firm conducted between February 8-12, 1999, Consumer Safety Officer Martina E. Ctrnacty determined your firm manufactures sterile disposable surgical instruments, including a disposable clamp cover, Disposa-Loops, Disposa-Boots, and the Whisk'R. These products are devices within the meaning of Section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

The above-stated 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 the manufacturing, packing, storage, or installation are not in conformance with the Quality System Regulation (QSR), as specified in Title 21, Code of Federal Regulations, Part 820 (21 CFR 820) as follows:

1. Failure of management to establish a quality policy as required by 21 CFR 820.20(a). For example, the quality policy has not been signed or released by management.
2. Failure of management to establish a quality system and procedures, as required by 21 CFR 820.20(e). For example, the quality manual is in draft form and has not been completed, signed, or released.
3. Failure of management with executive responsibility to document the appointment of a member of management who, irrespective of other responsibilities, shall have established

authority over and responsibility for ensuring that the quality system requirements are effectively established and maintained, and reporting on the performance of the quality system to management, as required by 21 CFR 820.20(b)(3).

4. Failure of management to establish procedures for management review to ensure that the quality system satisfies the QSR requirements and your established quality policy and objectives, as required by 21 CFR 820.20(c). For example, your procedures for management review are not completed, signed, or released.
5. Failure to establish and maintain procedures for implementing corrective and preventative action as required by 21 CFR 820.100(a). Specifically, corrective and preventative action procedures have not been completed, signed, or released.
6. Failure of management to establish procedures for receiving, reviewing, and evaluating complaints by a formally designated unit, as required by 21 CFR 820.198(a). For example, your complaint procedure has not been completed, signed or released.
7. Failure of management to establish and maintain procedures to control product that does not conform to specified requirements, as required by 21 CFR 820.90(a). For example, your procedures to control nonconforming product have not been completed, signed, or released.
8. Failure of management to establish and maintain instructions and procedures for performing and verifying that the servicing meets specified requirements, as required by 21 CFR 820.200(a).
9. Failure of management to establish procedures for quality 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, as required by 21 CFR 820.22. Specifically, your quality audit procedures have not been completed, signed, or released.
10. Failure of management to establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met, as required by 21 CFR 820.30(a).

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.

We acknowledge your response dated March 3, 1999, to the observations noted on the FD-483, which states that you will correct all items on the FD-483 by April 1, 1999, with the exception of item 8, which will be completed by June 1, 1999. Your response is not adequate in that it simply

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NOTHING PURGED**

March 24, 1999

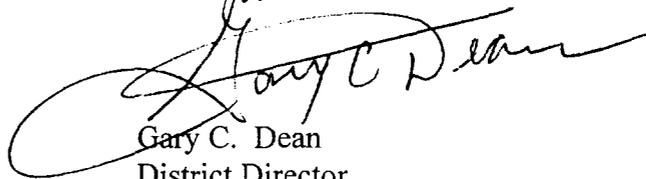
states the violative conditions will be corrected, and does not give any indication as to how you plan to bring your firm into compliance. We will determine the adequacy of these corrections on our next inspection.

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 any 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,



Gary C. Dean
District Director

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