



0120336

August 27, 1998

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

WARNING LETTER
CHI-37-98

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

James V. D'Alise, D.D.S., President
Duo-Dent Dental Implant Systems L.L.C.
340 W. Butterfield Road, Suite 2-C
Elmhurst, IL 60126

Dear Dr. D'Alise:

During the inspection of your firm from August 4 to 5, 1998, Investigator Tamara Alicea determined your firm manufactures dental implant kits. Dental implant kits are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The inspection revealed that your 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 Quality System Regulation (QSR) for Medical Devices, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to validate the integrity of packaging for the sterile components of dental implant kits.
2. Failure to maintain written procedures for design control requirements.
3. Failure to follow your procedure for audit of your contract sterilizer. The procedure calls for audit of the contract sterilizer on an annual basis. There is no documentation that audits are being completed as required by the procedure.

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 Form FDA 483 issued to you 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 award of contracts.



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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 Stephen D. Eich, Compliance Officer.

Sincerely,

\s\
Raymond V. Mlecko
District Director