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

September 26, 2001

WARNING LETTER
CHI-54-01

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. John W. Martin, President
Cameron-Miller, Inc.
3949 S. Racine Ave.
Chicago, IL 60609

Dear Mr. Martin:

During an inspection of your firm from March 14 to March 20, 2001, Investigator Tamara Brey determined that your establishment manufactures electrosurgical units and accessories. These products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The 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 regulation for medical devices, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to establish a quality plan that defines the quality practices, resources, and activities relevant to devices that are designed and manufactured.
2. Failure to establish quality system procedures and instructions.
3. Failure of management with executive responsibility to review the suitability and effectiveness of the quality system. Failure to establish procedures for management review of the quality system.
4. Failure to establish and maintain procedures for implementing corrective and preventive action.
5. Failure to establish a Device Master Record that includes specifications for labeling and packaging.

6. Failure to include the primary identification label and other labeling used for each production unit.

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, Inspectional Observations, issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your establishment's quality system. You are responsible for investigating and determining the causes of the violations identified by the FDA. You also must promptly initiate permanent corrective and preventive action on your Quality System.

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 Quality System/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.

We request that you 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 30 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 30 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, at the above address.

Sincerely,

\s\
Raymond V. Mlecko
District Director