



DEPARTMENT OF HEALTH & HUMAN SERVICES

M 335 N, Pd R

10/29/97

10/8/97 RB

Certified/Return Receipt Requested

October 7, 1997

Food and Drug Administration
Kansas City District Office
11630 West 80th Street
P.O. Box 15905
Lenexa, Kansas 66285-5905

Telephone: (913) 752-2100

WARNING LETTER

Eugene Lipsky, President
International Medical Electronics LTD.
3939 Broadway
Kansas City, MO 64111

Ref.# - 98-KAN-002

Dear Mr. Lipsky:

During an inspection of your firm located in Kansas City, Missouri, on August 18 through September 12, 1997, our investigator determined that your firm is a specifications developer for a shortwave diathermy device. A shortwave diathermy is device as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (Act).

The above-stated inspection revealed that this device is 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 current good manufacturing practice (CGMP) requirement of the Quality System Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, to include, but not limited to, the following:

1. Failure to maintain a complaint system which would include review and investigation, corrective action, and documentation of all complaints [21 CFR 820.198]. This would also be a violation of the Quality System Regulation, 21 CFR 820.198.
2. Failure to have an established quality audit program [21 CFR 820.20(b)]. This would also be a violation of the Quality System Regulation, 21 CFR 820.22.

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3. Failure to have an established program to handle changes in product specifications, processes and procedures [21 CFR 820.100]. This would also be a violation of the Quality System Regulation, 21 CFR 820.30.
4. Failure to have an established Quality Policy. This is a violation of the Quality System Regulation, 21 CFR 820.20(a).
5. Failure to have an established Quality Plan. This is a violation of the Quality System Regulation, 21 CFR 820.20(d).
6. Failure to have any established Quality Procedures. This is a violation of the Quality System Regulation, 21 CFR 820.20(e).

At the conclusion of the inspection Form FDA 483, Inspectional Observations, was prepared, issued to and discussed with you.

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 have received and reviewed a letter from Mr. Jeffrey H. Lipsky, Vice President dated September 15, 1997, which is a response to the Form FDA 483 observations. The letter was reviewed prior to the issuance of this letter. It appears from the letter that proper steps are being taken to correct the noted deviations.

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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Additionally, no premarket submissions for devices to which the 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 FDA 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 any additional steps you have taken, in addition to those listed in the September 15 letter, to correct the noted violations.

Include 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 reply should be sent to Clarence R. Pendleton, Compliance Officer, at the above address.

Sincerely,

W. Michael Rogers
District Director
Kansas City District

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HFC-210; HFC-240(MPQAS); RRW; RF

CRP:tlw