



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Baltimore District Office
6000 Metro Drive
Suite 101
Baltimore, MD 21215-3215
Telephone: (410) 773-5454

WARNING LETTER

03-BLT-18

June 16, 2003

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Dr. David T. Krausman, CEO
Individual Monitoring Systems, Inc.
1055 Taylor Ave., Suite 300
Baltimore, MD 21238

Dear Dr. Krausman:

During an inspection of your establishment located in Baltimore, Maryland on April 22 through May 1, 2003, our investigator determined that your establishment manufactures activity recording devices. Activity recording devices are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 USC 321(h)].

The above-stated inspection revealed that these devices are adulterated within the meaning of 501(h) of the Act [21 USC 351(h)] 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 regulations for medical devices specified in 21 Code of Federal Regulations (CFR) Part 820 as follows:

1. Your firm failed to analyze sources of quality data to identify existing and potential causes of nonconforming product or other quality problems as required by 21 CFR §§ 820.90 & 820.100(a).
2. Your firm failed to document corrective and preventative actions including analysis of sources of quality data, investigations of causes of nonconformities, and the actions needed to correct or prevent recurrence of nonconforming product and other quality problems as required by 21 CFR § 820.100(b).
3. Your firm failed to establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements as required by 21 CFR §§ 820.50 & 820.80.

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4. Your firm failed to establish and maintain procedures for the documentation, validation, review, and approval of design changes implemented for your PAM RL device as required by 21 CFR § 820.30(i).

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 on the Form FDA-483 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 are also responsible for conducting internal audits to identify any deviations from the Quality System Regulation. You must promptly initiate permanent corrective and preventive actions 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.

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.

We acknowledge your response letter dated May 12, 2003 to the observations noted on the FDA-483 issued on May 1, 2003. Your response will be added to your official file and the corrective actions outlined in the response will be verified during the next inspection of your facility. The response we received does not contain sufficient specific information regarding your corrective actions to make an accurate evaluation.

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 Steven B. Barber, Compliance Officer, Food and Drug Administration, 6000 Metro Drive, Suite 101, Baltimore, MD 21215.

Sincerely,

/s/

Lee Bowers
District Director
Baltimore District

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cc: Ms. Roberta Allen, President
Individual Monitoring Systems, Inc.
1507 Ritchie Highway, Suite 103
Arnold, MD 21012