



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

2/16/97
Bff
D1080B

Dallas District
3310 Live Oak Street
Dallas, Texas 75204-6191

January 8, 1997

Ref: 97-DAL-WL-12

WARNING LETTER

Certified Mail
Return Receipt Requested

Mr. Kenneth F. Perdue, Chairman
EPIC Medical Equipment Services, Inc.
4643 Westgrove Drive
Dallas, Texas 75248

Dear Mr. Perdue:

During an inspection of your firm located in Dallas, Texas, on August 13 through 23, 1996, the Texas Department of Health investigator (under contract to the Food and Drug Administration) determined that your firm manufactures pulse oximeter finger sensors and cables. These products are devices as defined by Section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

The above referenced 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 their manufacturing, packing, storage, or installation are not in conformance with the Good Manufacturing Practice (GMP) for Medical Devices Regulations, as specified in Title 21, Code of Federal Regulations (21 CFR), Part 820, as follows:

1. Failure to review, evaluate, and maintain by a formally designated unit all records of written and oral complaints relative to the identity, quality, reliability, safety, effectiveness, or performance of a device. To determine whether or not a complaint investigation is necessary, and when no investigation is necessary to include the reason and the name of the individual responsible for the decision not to investigate, as required by 21 CFR 820.198(a).

For example, review of Warranty Return documents dated March through July 1996, revealed approximately 805 devices were returned for various reasons, including: intermittent connections, damaged cables and connectors, missing

springs, and broken or damaged clips. Only thirteen (13) of the 805 returns were reviewed, evaluated and maintained as complaints.

2. Failure to investigate any failure of a device to meet performance specifications after the device has been released for distribution, as required by 21 CFR 820.162.

For example, none of the 805 above referenced device returns resulted in a failure investigation.

3. Failure to have in place an adequate organizational structure and sufficient personnel to assure that the devices you produce are manufactured in accordance with the requirements of the GMP regulation, as required by 21 CFR 820.20.

For example, your firm failed to formally establish a quality assurance program, designate quality assurance personnel and conduct quality assurance audits of either EPIC's or your contract manufacturer's facilities.

4. Failure to have written procedures for finished device inspection to assure that device specifications are met as required by 21 CFR 820.160.

For example, twenty-one (21) of twenty-seven (27) devices failed to have finished device inspection procedures.

5. Failure to establish, implement, and control written reprocessing specifications and processing procedures to assure that the reprocessed devices or components meet the original, or subsequently modified and approved specifications, as required by 21 CFR 820.115.

For example, your firm did not establish, implement, and control written rework procedures for finger sensors that failed in the field and were subsequently returned to the firm, or incoming contract manufactured devices that failed finished device testing.

In addition to the above stated GMP violations, thirteen (13) of your firm's devices (Model No.s E103-01, E112-02, E112-03, E112-04, E112-05, F112-06, E112-08, E112-09, E112-10, E112-11, E112-12, E112-13, and E112-14) are adulterated within the meaning of Section 501(f)(1)(B) of the Act in that they are Class III devices under Section 513(f) in that they do not have approved applications for premarket approval (PMA) pursuant to Section 515(a) or approved applications for investigational device exemptions (IDE) under Section 520(g). These devices are also misbranded within the meaning of Section 502(o) of the Act in that a notice or other information respecting the devices was not provided to FDA as required by Section 510(k). Your firm may submit either one (1) Section 510(k) submission for the thirteen (13) above referenced models or thirteen (13) separate 510(k) submissions.

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EPIC Medical Equipment Services, Inc.

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.

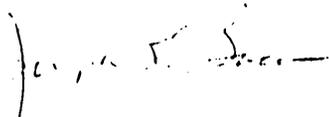
Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for devices to which the GMP violations are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates for Products for Export will be approved until the violations related to the subject device 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 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 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 fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed.

Your response to this letter should be sent to James Austin Templer, Compliance Officer, at the above letterhead address.

Sincerely yours,



Joseph R. Baca
Dallas District Director