



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Public Health Service
Food and Drug Administration

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

May 20, 1998

Ref: 98-DAL-WL-36

WARNING LETTER

**VIA FACSIMILE AND
FEDERAL EXPRESS**

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 April 13 through 29, 1998, our investigator 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 Current Good Manufacturing Practice (CGMP) requirements for devices as set forth in the Quality Systems Regulation specified in Title 21, Code of Federal Regulations (21 CFR), Part 820, as follows:

1. Failure to document, review, and evaluate complaints, and to conduct failure investigations where necessary, as required by 820.198(b) and (c). For example, repair data indicates numerous defective finger clips, however, there is no documentation indicating that the data was reviewed, evaluated, and investigated to determine the cause(s) of the failures.
2. Failure to establish component specifications, as required by 820.181(a). For example, Light Emitter Diode (LED) component [REDACTED] specifications were not established.

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3. Failure to document the evaluation and disposition of nonconforming product, as required by 820.90. For example, numerous sensors were rejected during July and August of 1997, without evaluation and disposition documentation.
4. Failure to establish finished device acceptance procedures, as required by 820.80(d). For example, your firm failed to establish finished device testing or inspection for the Model E400 pulse oximeter sensor series.
5. Failure to document changes to records, as required by 820.40(b). For example, between February and October 1997, the sensor sampling plan was changed without documentation.
6. Failure to use a sampling plan based upon a valid statistical rationale, as required by 820.250(b). For example, your firm failed to follow the referenced [REDACTED] when preparing procedure #G1025, "Inspection Sampling Plan Procedure."
7. Failure to ensure that test equipment is suitable for its intended purpose(s), as required by 820.72(a). For example, circuit analyzers and oscilloscopes are not calibrated in accordance with the time frames established in your approved procedures.

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.

Until these violations are corrected, and FDA has documentation to establish that such corrections have been made, Federal agencies will be advised of the issuance of this Warning Letter so that they may take this information into account when considering the award of contracts.

To facilitate FDA's determination that corrections have been made and thereby enable FDA to withdraw its advisory to other Federal agencies concerning the award of government contracts for products manufactured at your Dallas, Texas facility, we are requesting that you submit to this office a certification by an outside expert consultant verifying that they have conducted an audit of your firm's manufacturing and quality assurance systems relative to the CGMP requirements of the QSR set forth in 21 CFR, Part 820. On or before November 20, 1998, you should submit a copy of the consultant's report, and certification by your firm's CEO (if other than yourself) that he or she has

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reviewed the consultant's report and that your firm has initiated or completed all corrections called for in the report. The enclosed guidance may be helpful in selecting an appropriate consultant.

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.

In addition to the above stated CGMP violations, our initial review indicates that significant modifications have been made to the design (e.g., photo diode [REDACTED] and [REDACTED] or intended use (e.g., use on the ear and foot) of the E200 and E400 sensor series. These changes may require Section 510(k) premarket notification submissions. You should consult with the FDA's Center for Devices and Radiological Health, Office of Device Evaluation regarding the need for additional Section 510(k) submissions.

We acknowledge receipt of your May 19, 1998, response to our inspectional observations and we are currently evaluating the adequacy of your proposed corrections. Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to identify and correct 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 frame within which the corrections will be completed.

Your reply should be directed to James Austin Templer, Compliance Officer, at the above letterhead address.

Sincerely yours,



Joseph R. Baca
Dallas District Director

Enclosure