



DEPARTMENT OF HEALTH & HUMAN SERVICES

HF 1-35 3/2/98

Public Health Service
D 1441 B

Food and Drug Administration
1141 Central Parkway
Cincinnati, OH 45202

February 24, 1998

WARNING LETTER
CIN-WL-98-181

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

John E. Trybuski, President
Scottcare Corporation
4971 West 150th Street
Cleveland, OH 44135

Dear Mr. Trybuski:

On January 21 to 30th, 1998, the Food and Drug Administration (FDA) conducted an inspection of your firm which manufactures the Tele-Rehab II Cardiopulmonary Monitoring System. The cardiac monitor is a device as defined by Section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

The investigator found deviations from the Quality System Regulation, Good Manufacturing Practice (GMP) for Medical Devices as listed in Part 820 of Title 21, Code of Federal Regulations (CFR). This causes the Tele-Rehab II Cardiopulmonary Monitoring System to be 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 and storage are not in conformance with the Quality System Regulation, Part 820.

The following deviations from the Device Quality System Regulations were documented:

- Failure to conduct planned and periodic audits of the quality and production system.
- Failure to maintain a Device Master Record (DMR).
- Failure to maintain a complete Device History Record (DHR) in that it does not contain updates to software or their location, or document rework and evaluation of non-conforming finished devices or parts.
- Failure to have a complete complaint procedure in that it does not include how complaints are reviewed and evaluated; complaints are not documented as being reviewed; documentation of why an investigation was not conducted; and records of

corrective actions or follow-up records of corrective actions or follow-up conducted are not consistently recorded in the complaint system.

- Failure to establish a Medical Device Reporting (MDR) Procedure.
- Failure to date and sign, as approved, all Quality Control Procedures.
- Failure to establish and maintain complete procedures for implementing corrective and preventive actions. It is incomplete in that the procedure does not address requirements for analyzing processes, work operations, quality audit reports and complaints to identify existing and potential causes of nonconforming products.
- Failure to calibrate instruments used during production and testing according to written procedures. Also, records are not being maintained for equipment that is reported to be calibrated.
- Failure to establish procedures or controls taken for Electrostatic Discharge (ESD) during the circuit board assembly process.

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 into account when considering the award of contracts. 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 FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

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Please notify this office within fifteen days of receipt of this letter of the specific steps you will be taking to comply with our request.

Your response should be sent to Lawrence E. Boyd, Compliance Officer, Food and Drug Administration, 1141 Central Parkway, Cincinnati, Ohio, 45202.

Sincerely,



Diana J. Kolaitis
Acting District Director
Cincinnati District

LEB/pjk