



September 17, 2004

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

WARNING LETTER

Ref. KAN 2004-17

Mr. Damian W. Enneking, Jr.
President
Enneking Medical Inc.
1801 Guinotte Avenue
Kansas City, MO 64120

Dear Mr. Enneking:

During an inspection of your establishment, on July 27 through August 2, 2004, our investigators determined that you manufacture whirlpool systems which may include integrated disinfectant systems, an ultrasonic option, patient lifts and/or patient scales. These products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The 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 manufacture, packing, storage, or installation are not in conformity with applicable current Good Manufacturing Practice (cGMP) requirements, which are set forth in FDA's Quality Systems (QS) Regulation, codified at Title 21, Code of Federal Regulations (CFR), Part 820. Specifically:

Failure to establish and maintain procedures for implementing corrective and preventive action [21 CFR 820.100]. Your firm does not consistently investigate the failure of a device to meet performance specifications after a device has been released for distribution, and make a written record of the investigation including conclusions and follow-up. Such investigations should address the cause of nonconformities relating to product, processes, and the quality system.

Failure to establish and maintain a complaint handling system [21 CFR 820.198]. Complaint handling procedures for receiving, reviewing, and evaluating complaints have not been established. Complete complaint files are not maintained. Complaints involving

the possible failure of a device to meet any of its specifications were not reviewed, evaluated, and investigated where necessary.

Failure to develop, maintain, and implement written Medical Device Reporting procedures [21 CFR 803.17].

Failure to establish a formal quality system [CFR 820.20]. You have not established a quality policy and objectives for, and commitment to, quality. You have not established procedures for management with executive responsibility to review the suitability and effectiveness of the quality system.

Failure to establish and maintain procedures to control the design of the device to ensure that specified design requirements are met [21 CFR 820.30]. Procedures were not established for the identification, documentation, validation or verification, review, and approval of design changes before their implementation.

Certain measuring and test equipment is not suitable for its intended purposes or capable of producing valid results [21 CFR 820.72(a)]. Case to Ground Leakage Current test specification is 300 μ A. Your "RLI-300 C" Ohmic Instrument used for testing Case to Ground Leakage Current on your whirlpool tubs and patient lifts is only able to achieve a 200 μ A reading.

Failure to maintain device history records all devices to demonstrate that the devices are manufactured in accordance with the device master record [21 CFR 820.184]. Procedures have not been established to ensure that device history records for each batch, lot, or unit are maintained to demonstrate that the device is manufactured in accordance with the device master record and the Quality Systems regulation. Device history records do not routinely include manufacturing dates.

For your clarification, 21 CFR Part 880.5500 defines an AC-powered patient lift; 21 CFR Part 880.5510 similarly defines a non-AC-powered patient lift; 21 CFR Part 880.2720 defines a patient scale; and 21 CFR Part 890.5100 defines a whirlpool tub (immersion hydrobath).

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 applicable requirement of the Act and of FDA regulations. The specific violation noted in this letter and in the Form FDA 483 provided to you at the close 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 FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

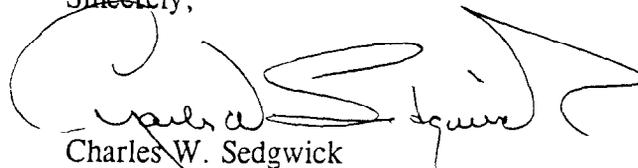
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You should take prompt action to correct this deviation. Failure to do so may result in FDA regulatory action without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties. Federal agencies are advised of the issuance of all Warning Letters about medical 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 violation above is reasonably related will be cleared or approved until the violation has been corrected. Also, no requests for Certificates to Foreign Governments will be approved until the violation related to the subject devices has been corrected.

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 reply should be sent to Nadine Nanko Johnson, Compliance Officer, at the above address.

Sincerely,

A handwritten signature in black ink, appearing to read "Charles W. Sedgwick", written over a horizontal line.

Charles W. Sedgwick
District Director
Kansas City District