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VIA FEDERAL EXPRESS

**Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, FL 32751**

WARNING LETTER

FLA-02-37

April 25, 2002

Walter E. Blankley, CEO
Ametek, Inc.
Station Square
Paoli, Pennsylvania 19301

Dear Mr. Blankley:

During an inspection of your establishment located in Largo, Florida on February 13-14, 2002, FDA Investigator Ronald T. Weber determined that your establishment is a manufacturer of dynamometers. Under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), dynamometers are medical devices that are used to assess neuromuscular function or degree of neuromuscular blockage, by measuring with a force transducer, to diagnose a medical condition of the body. The investigator documented violations of the Act causing the device(s) to be adulterated within the meaning of section 501(h) of the Act. The Act requires that manufacturers conform to the Quality System (QS) Regulation for medical devices, as specified in Title 21, Code of Federal Regulations (CFR), Part 820. The above-stated inspection revealed that the device(s) are adulterated 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 Regulation as follows:

1. Your firm failed to establish, maintain, and implement a corrective and preventive action procedure as required by 21 CFR 820.100(a). For example, your firm has no CAPA procedures as defined by the Quality System regulations including: failure investigations, procedures to analyze quality data, procedures to verify/validate corrections, procedures that ensure that information related to quality problems is disseminated and for submitting relevant information on identified quality problems for management for review (FDA 483, Item #1).
2. Your firm failed to establish and maintain procedures to control the design of device(s) in order to ensure that specified design requirements are met as required by 21 CFR 820.30. For example, there are no procedures for design validation, design transfer, or design changes made as a result of design inputs, and no requirement that inputs be approved by the design review committee (FDA 483, Item #2).

3. Your firm failed to validate the results of processes that cannot be verified by a subsequent inspection or test as required by 21 CFR 820.75. For example, your soldering process has not been validated (FDA 483, Item #4).
4. Your firm failed to establish and maintain procedures for receiving, reviewing, and evaluating complaints as required by 21 CFR 820.198(a) (FDA 483, Item #5).
5. Your firm failed to establish procedures for identifying training needs and ensuring that all personnel are trained to adequately perform their assigned duties as required by 21 CFR 820.25(b). For example, no one at your firm has received training in the Quality Systems Regulations, and is therefore, qualified to conduct training with respect to the Quality Systems Regulations (FDA 483, Item #6).

MEDICAL DEVICE REPORTING

Your devices are misbranded within the meaning of section 502(t)(2) in that there was a failure to furnish material or information required by or under section 519 respecting the devices. These violations include, but are not limited to the following:

6. Your firm failed to establish and maintain written procedures for Medical Device Reporting as required by 21 CFR 803.17 (FDA 483, Item #3).

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 its regulations.

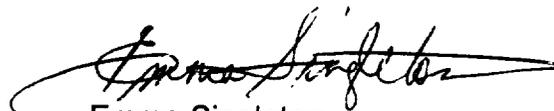
Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for Class III devices to which QS regulation deficiencies are reasonably related will be 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 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.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of the steps you have taken to correct the noted violations, including (1) the time frames within which the corrections will be completed, (2) any documentation indicating the corrections have been achieved, and (3) 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.

Your response should be sent to Timothy J. Couzins, Compliance Officer, Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, (407) 475-4728.

Sincerely,

A handwritten signature in black ink, appearing to read "Emma Singleton", with a long horizontal flourish extending to the right.

Emma Singleton
Director, Florida District