DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

950010

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

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-04-40

August 20, 2004

David P. Lewing, President
Medical Energy, Inc.
225 East Zaragoza Street
Pensacola, Florida 32501-6048

Dear Mr. Lewing:

During an inspection of your establishment located at 225 East Zaragoza Street, Pensacola, Florida on June 2 through 5, 2004, FDA Investigator Leo J. Lagrotte determined that your firm manufacturers the Laserforce diode medical laser and laser optical fibers used in invasive surgical procedures, which are devices as defined by section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), [21 U.S.C. 321(h)].

The investigator documented significant violations from the Quality System (QS) Regulation, Title 21, Code of Federal Regulations (CFR), part 820. These violations cause the devices you manufacture to be adulterated within the meaning of Section 501(h) [21 U.S.C. 351(h)] of the Act.

The investigator noted the following violations of the QS regulations:

1. Management with executive responsibility shall establish its policy and objectives for, and commitment to, quality, and shall ensure that the quality policy is understood, implemented, and maintained at all levels of the organization as required by 21 CFR 820.20. Your firm has manufactured devices continuously since1996, the implementation date of the Quality System Regulation, but failed to implement a quality system until May 16, 2003. Your quality system still has not been implemented fully. For example, procedures for acceptance or rejection of finished product have not been established; sterilization validation has not been conducted; process controls do not provide for monitoring and control of process parameters; and quality audits have not been conducted. (FDA 483, Item #1).

2. Management with executive responsibility shall review the suitability and effectiveness of the quality system at defined intervals and with sufficient frequency according to established procedures to ensure that the quality system satisfies the requirements of the QS regulation and the manufacturer's established quality policy and objectives. The dates and results of the quality system reviews shall be documented as required by 21 CFR 820.20(c). Your firm failed to conduct an [redacted] management review and [redacted] communication meetings as required by your quality manual (FDA 483, Item #14).

3. Each manufacturer shall conduct quality audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system as required by 21 CFR 820.22. Your firm scheduled [redacted] internal quality audits to be performed [redacted] per month from July 2003 through July 2004. Only three of the scheduled internal audits were conducted in that time (FDA 483, Item #8).

4. Where the results of a process cannot be fully verified by subsequent inspection and test, the process shall be validated with a high degree of assurance and approved according to established procedures as required by 21 CFR 820.75(a). Your firm sterilizes optical fiber laser delivery systems using [redacted] EtO sterilizers ([redacted]) that have never been validated. Your firm also cleans and resterilizes opened, but unused fibers or fibers whose sterility date has expired. In addition, there are no written procedures addressing acceptance, cleaning and resterilization of these fibers and the cleaning and resterilization operations have not been validated (FDA 483, Item #5).

5. Each manufacturer shall develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications as required by 21 CFR 820.70(a). That regulation also states that where deviations from device specifications could occur as a result of the manufacturing process, the manufacturer shall establish and maintain process control procedures that describe any process controls necessary to ensure conformance to specifications. Your firm identified four critical manufacturing points that require inspection and approval, including 1) the [redacted] is clean and inspected after installation, 2) inspection of end tip after processing, 3) inspection of fiber after the handpiece is attached and before packaging, and 4) after sterile packaging. Process control procedures have not been established for these processes (FDA 483, Item #4).

6. Each manufacturer shall establish and maintain procedures for finished device acceptance to ensure that each production run, lot, or batch of finished devices meets acceptance criteria as required by 21 CFR 820.80(d). Your firm's quality systems manual and processing procedures fail to address the need for finished device acceptance and release. The device history records identified as "Fiber Assembly Traveler" that the FDA investigator reviewed all failed to include sign off by the designated individual approving the devices for final release (FDA 483, Item #3).

7. Each manufacturer shall establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements as required by 21 CFR 820.50. Inspection of incoming components is limited to visual examination and no testing is performed on a regular basis to determine that components meet specifications and quality requirements (FDA 483, Item #10). In addition, each manufacturer shall define the type and extent of control it will exercise over suppliers and contractors, based on the results of documented evaluations of the suppliers' and contractors' ability to meet specified requirements, as required by 21 CFR 820.50(a)(1)&(2). Your firm reported that on-site quality audits of component suppliers were performed; however, criteria for the audits were not established and the on-site audits were not documented (FDA 483, Item #11).

8. The equipment identification, calibration dates, the individual performing each calibration, and the next calibration date shall be documented as required by 21 CFR 820.72(b)(2). Documentation of the calibration of test equipment, calipers, voltage meters and power meters is incomplete or not maintained (FDA 483, Item #15).

9. Each manufacturer shall establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met as required by 21 CFR 820.30 as follows:

    a) Each manufacturer shall establish and maintain plans that describe or reference the design and development activities and define responsibility for implementation as required by 21 CFR 820.30(b). Your firm has not established and implemented a design and development plan for the Lightforce 20-30 watt diode medical laser and all models of the Laser Powertouch quartz contact delivery system (FDA 483, Item #9).

b) Each manufacturer shall establish and maintain procedures for validating the device design as required by 21 CFR 820.30(g). Your firm failed to document the results of design validation, including identification of the design, methods, the date and the individual(s) performing the validation (FDA 483, Item #2).

c) Each manufacturer shall establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation as required by 21 CFR 820.30(i). Changes to the design and procedures for the attachment of fibers to the hand piece were not validated, reviewed or documented prior to the changes being implemented (FDA 483, Item #7).

10. Each manufacturer shall establish procedures for identifying training needs and ensure that all personnel are trained to adequately perform their assigned responsibilities and the training shall be documented as required by 21 CFR 820.25(a) & (b). Your firm trains employees on-the-job until they are able to perform the assigned duties; however, training and the successful completion of training is not documented (FDA 483, Item #12).

11. Each manufacturer shall establish and maintain procedures to control labeling activities as required by 21 CFR 820.120(b). You have not established adequate control of labeling procedures for optical fibers, for example, you print the warning logo-type labels used for the lasers without procedures. (FDA 483, Item #16).

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. 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.

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. 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 to Foreign Governments will be approved until the violations related to the subject devices have been corrected.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of any steps that you are still in the process of taking 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,

for Elizabeth W. Arnold

Emma Singleton
Director, Florida District