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**VIA FEDERAL EXPRESS**

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

**WARNING LETTER**

FLA-02-10

October 29, 2001

Paul A. Baker, President  
Medical Device Technologies, Inc.  
3600 S.W. 47<sup>th</sup> Avenue  
Gainesville, Florida 32608

Dear Mr. Baker:

During an inspection of your establishment located in Gainesville, Florida on September 10-14, 2001, FDA Investigator R. Kevin Vogel determined that your establishment is a manufacturer and distributor of needles and catheters including bone marrow sets, hystero-salpingography (HS) and Seldinger needle tests, which are medical devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

Under the Federal Food, Drug, and Cosmetic Act (the Act), the products that your firm manufactures are considered to be medical devices that are used to diagnose or treat medical conditions or to affect the structure or function of the body. The law 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 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 manufacturing, packing, storage, or installation are not in conformance with the Quality System Regulation for medical devices, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Your firm's quality audits fail to verify that your quality system is effective as required by 21 CFR 820.22. For example, your firm's internal audit dated August 20, 2001 failed to identify and correct objectionable conditions documented on the Inspectional Observations (FDA 483) issued to Karl B. Swartz, Quality Assurance Manager on September 14, 2001 (FDA 483, Item #1).

2. Your firm failed to establish and maintain the requirements, including quality requirements that must be met by potential suppliers and contractors as required by 21 CFR 820.50(a)(1). For example, your purchasing control procedures fail to verify all specifications for vendor supplied devices and/or components, your firm failed to assure adequate process validation of molding of breast localization needle hubs at the contract manufacturer, and you failed to require periodic supplier audits (FDA 483, Item #2a-c).
3. Your firm failed to identify action(s) needed to correct and prevent recurrence of non-conforming product and other quality problems as required by 21 CFR 820.100(a)(3). For example, your purchasing control procedures are inadequate because complaints related to a vendor supplied product were not adequately addressed and resulted in a recall of the device(s) (FDA 483, Item #4).
4. Your firm failed to verify or validate the corrective and preventive actions to ensure that such action is effective and does not adversely affect the finished device as required by 21 CFR 820.100(a)(4). For example, you failed to verify/validate preventive action taken at a supplier after receiving complaints that reported needles breaking off at the hub, and you failed to document and verify preventive action taken in response to complaints of biopsy needles (FDA 483, Item #5).
5. Your firm failed to analyze, identify and document existing and potential causes of non-conforming product and other quality problems as required by 21 CFR 820.100(a)(1). For example, you failed to complete analysis of service reports to determine corrective and preventive action, you failed to identify and investigate service reports as complaints, your analysis of complaints does not include the actual number of defects and analysis of complaints fail to trend complaints by failure code (FDA 483, Item #6, 7 & 8)
6. Your firm failed to validate the aeration process following sterilization with a high degree of assurance that it is approved according to established procedures as required by 21 CFR 820.75. For example, validation of the capabilities of the aeration room at your contract sterilizer was determined with only one device being checked for EtO residues on which your specification was based (FDA 483, Item #11).
7. Your firm failed to document the evaluation or investigation of non-conforming product as required by 21 CFR 820.90(a). For example, you failed to document investigations of gamma sterilization failures of dose audits dated May 21, 1998 and June 26, 1998 (FDA 483, Item #12).

8. Your firm failed to confirm that design output meets design input requirements as required by 21 CFR 820.30(f). For example, you failed to complete testing of specific device characteristics to ensure verification of the design (FDA 483, Item #3).

#### 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:

9. Your firm failed to submit an MDR report within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device may have caused or contributed to a death or serious injury as required for 21 CFR 803.50(a)(1). For example, you failed to submit a MDR to FDA covering Complaint #522 dated April 24, 2001 referencing a bone marrow needle that pushed through the plastic hub and punctured the physician's hand. You also failed to submit an MDR to FDA covering Complaint #259 dated May 11, 1998 covering a biopsy needle that broke off in the bone of a patient, which required intervention to remove the needle to prevent serious injury.
10. Your firm's written MDR procedure fails to include an internal system to determine when a reported event meets the criteria for reporting under the MDR regulation as required by 21 CFR 803.17(a)(2). For example, you failed to obtain necessary information to adequately assess complaints resulting in serious injury or death for the purpose of making MDR reports to the FDA (FDA 483, Item #10).

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.

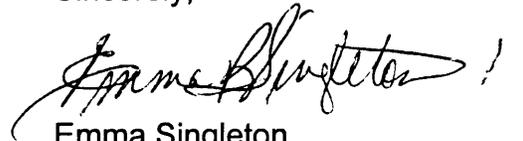
We have received and reviewed your firm's response dated September 21, 2001, which promises corrective action. Your response is inadequate because it fails to provide a timeline when corrective actions will be made, there is no documentation showing corrective actions taken nor does your response describe any specific actions taken. Your response will be placed in our permanent establishment file.

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 any steps you may have taken to correct the noted violations, including (1) the time frames within which the corrections will be completed if different from those annotated on the FDA 483, (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". The signature is fluid and cursive, with a long horizontal stroke at the end.

Emma Singleton  
Director, Florida District