



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

94939d

San Francisco District  
1431 Harbor Bay Parkway  
Alameda, CA 94502-7070  
Telephone: 510/337-6700

August 30, 2004

Via FEDEX

Melbourne Kimsey II  
President  
Medical Device Resource Corporation  
23392 Connecticut Street  
Hayward, CA 94545

**WARNING LETTER**

Dear Mr. Kimsey:

Our review of information collected during an inspection of your firm's operations located in Hayward, CA, from July 7 through July 22, 2004, revealed that your firm manufactures liposuction aspirator systems. These products are devices as defined in Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our inspection disclosed 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 manufacturing, packing, storage, or installation are not in conformance with the Good Manufacturing Practice (GMP) requirements of the Quality System (QS) Regulations for medical devices, as specified in Title 21, Code of Federal Regulations (CFR), Part 820 as follows:

1. Failure to adequately establish and maintain a quality system that is appropriate for the specific medical device designed or manufactured and that meets the requirements in 21 CFR Part 820, as required by 21 CFR 820.5. For example, management has not ensured that quality system requirements have been effectively established and maintained.
2. Failure of management with executive responsibility to establish its policy and objectives for, and commitment to, quality, as required by 21 CFR 820.20(a).
3. Failure for management with executive responsibility to 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 in 21 CFR 820 and the manufacturer's established quality policy and objectives, as required by 21 CFR 820.20(c). For example, you have failed to conduct management reviews.

4. Failure to define, document and implement procedures for 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. For example, you have no approved procedures for quality audits and you have failed to document the date and results of each quality audit, and reaudits where performed.
5. Failure to adequately establish (define, document and implement) and maintain procedures for implementing corrective and preventive actions, which include requirements for analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product or other quality problems, as required by 21 CFR 820.100(a)(1).
6. Failure to establish procedures defined for the identification, documentation, and validation or verification of design changes prior to their implementation, as required by 21 CFR 820.30(i). For example, the design change from the LS1000 model to the LS2 model included a change in the pump size which altered the [REDACTED], adding a second canister that increases the total volume of fat the respirator could store during one procedure and the use of a different type of safety valve to inhibit overflow of fat. You performed no design verification or validation activities for these changes.
7. Document control procedures have not been established and maintained, as required by 21 CFR 820.40. For example, the device master records fail to include or refer to the location of all device specifications, production process specifications, quality assurance procedures and packaging and labeling specifications, as required by 21 CFR 820.181.
8. Failure to establish (define, document and implement) and maintain procedures for acceptance of incoming products, as required by 21 CFE 820.80(b). For example, your procedure, the receiving Inspection Section of your QMS policy manual fails to define specific testing or inspection requirements, including acceptance criteria, for incoming products. In addition, not all incoming components are documented on the Incoming Inspection Log, nor is the disposition of rejected product documented on the Incoming Inspection Log as required by your procedures.
9. Failure to establish and maintain procedures for rework of nonconforming products, as required by 21 CFR 820.90(b)(2). For example, you fail to document in the Device History Record rework and reevaluation activities, including a determination of any adverse effect from the rework on the product.
10. Failure to 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. For example, you have no procedures for and have failed to establish specified requirements, including quality requirements, for the establishments that manufacture and stuff the printed circuit boards used in the LS2 liposuction aspirator.

11. Failure to establish and maintain procedures to ensure that equipment is routinely calibrated, as required by 21 CFR 820.72(a). For example, the vacuum gauge used for final acceptance testing of the LS2 Liposuction Aspirator has not been calibrated.

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 Form FDA-483 issued at the conclusion 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. You also must promptly initiate permanent corrective actions and preventative actions on your quality system.

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. Also, no requests for Certificates for Products for Export will be approved until the violations relating to the subject devices have been corrected.

You should take prompt action to correct these violations. Failure to promptly correct these violations 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 15 days of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make correction to any underlying systems problems necessary to assure that similar violations will not recur. Please include any and all documentation to show that adequate correction has been achieved. In the case of future corrections, an estimated date of completion, and documentation showing plans for correction, should be included with your response to this letter. Please address your response and any questions to the Food and Drug Administration, San Francisco District, 1431 Harbor Bay Parkway, Alameda, CA 94502, attention: Russell A. Campbell, Compliance Officer.

Should you require any assistance in understanding the contents of this letter, do not hesitate to contact Mr. Campbell at the above address or at 510-337-6861.

Sincerely yours,



Barbara J. Cassens  
District Director