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CERTIFIED MAIL
RETURN RECEIPT REQUESTED

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

WARNING LETTER

FLA-04-10

October 31, 2003

David A. Kendricks, President
Advantage Medical Electronics
10630 Wiles Road
Coral Springs, Florida 33076

Dear Mr. Kendricks:

During an inspection of your establishment located in Coral Springs, Florida on August 26-28, 2003, Investigator Salvatore N. Randazzo determined that your establishment is a manufacturer, rebuilder/refurbisher of patient monitoring cables and leadwires for use with ECG, EKG, SpO₂ and blood pressure monitoring devices (Class 2). These products are intended to be used by health practitioners to produce a visual display of the electrical signal(s) from the heart, brain and/or other organs for diagnosis and 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 of the Quality System (QS) Regulation, Title 21, Code of Federal Regulations (CFR), Part 820, and the medical device reporting regulations, Title 21, CFR, Part 803. These violations cause the devices you manufacture to be adulterated within the meaning of Section 501(h) [21 U.S.C. § 351(h)] and misbranded within the meaning of Section 502(t)(2) [21 U.S.C. § 352(t)(2)] of the Act.

Specifically, the investigator noted the following violations:

1. Your firm failed to document that you (1) investigated the cause of nonconformities relating to product and (2) identified the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems, as required by 21 CFR 820.100(a)(2), (3) and 820.100(b). Specifically, investigations and corrective and preventive actions taken in response to Customer Complaints>Returns identified in your "Material Return Authorization" (MRAs) from January 2003 through August 2003 were not documented (FDA 483, Item #1).

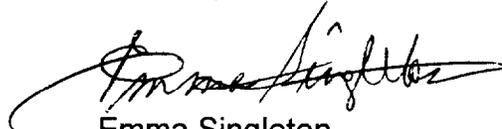
2. Your firm failed to validate, with a high degree of assurance, and failed to approve according to established procedures, a process whose results cannot be fully verified by subsequent inspection and test, as required by 21 CFR 820.75(a). Your firm failed to validate injection molding operations using five (5) pneumatic presses to manufacture connector and boot components (FDA 483, Item #6).
3. Your firm failed to document the results of in-process acceptance activities required by 21 CFR 820.80(c), as required by 21 CFR 820.80(e). Routine in-process testing of all ECG and SpO₂ cables manufactured at your facility is not documented, including the acceptance/rejection test results (FDA 483, Item #4).
4. Your firm failed to document the signature of the individual(s) conducting final acceptance activities required by 21 CFR 820.80(d), as required by 21 CFR 820.80(e). Cable devices were released for distribution without the signature of the individual designated to authorize release of finished product (FDA 483, Item #5).
5. Your firm failed to document scheduled adjustments, cleaning and other maintenance of equipment as required by 21 CFR 820.70(g)(1). Scheduled adjustments, cleaning or maintenance of the five (5) pneumatic presses were not documented (FDA 483, Item #7).
6. Your firm failed to document rework activities in the device history record (DHR), as required by 21 CFR 820.90(b)(2). Rework activities including retesting and reevaluation of nonconforming product to ensure that the product meets its current approved specifications were not documented (FDA 483, Item #3).
7. Your firm failed to develop, maintain, and implement written medical device report procedures as required by 21 CFR 803.17 (FDA 483, Item #2).

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 FDA 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 FDA 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 or approved 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.

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