



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Nashville District Office
297 Plus Park Blvd.
Nashville, TN 37217

June 22, 1999

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6/24/99
JEA

CERTIFIED MAIL – RETURN RECEIPT REQUESTED

Mr. Clifford E. Gammons, President
Adroit Medical Systems Inc.
1146 Carding Machine Rd.
Loudon, TN 37774

Warning Letter No. 99-NSV-16

Dear Mr. Gammons:

During an inspection of your firm located in London, Tennessee, on May 25-28, 1999, our investigator determined that your firm manufactures hypothermia/hyperthermia devices. Under the Federal Food, Drug, and Cosmetic Act (the Act), these products are considered to be medical devices because they are used to diagnose or treat a medical condition or to affect the structure or function of the body.

The above-stated inspection revealed 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, manufacture, packing, storage or installation are not in conformance with the Current Good Manufacturing Practice (CGMP) regulations of the Quality System Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820. The 1978 Good Manufacturing Practices (GMP) for Medical Device regulations were superceded on June 1, 1997, by the Quality System Regulation.

The inspection revealed the following deviations from 21 CFR Part 820:

1. A failure to investigate and adequately document complaints, including a lack of written complaint procedures;
2. A failure to always adequately document changes and a lack of written change control procedures;
3. A failure to assure that the contract sterilizer follows proper AAMI sterilization procedures for determining the proper verification dose for disk drapes and always uses the correct sterilization dose when disk drapes are sterilized;
4. A failure to evaluate component suppliers and to always follow component receiving and accepting procedures;

5. Your Standard Operating Procedures (SOPs) do not always agree with the procedures being used in the manufacturing of your products.

We acknowledge receipt of your responses dated June 2, 1999, and June 18, 1999, concerning our investigator's observations noted on the form FDA 483 issued at the conclusion of the May 25-28, 1999, inspection as well as discussion of the inspection between you and our investigator. We have reviewed your responses, and we need further information in regard to the items listed below:

1. Your response to item no. 1 does not state a procedure for handling Medical Device Reports (MDRs). This complaint procedure should reference time frames for reporting MDRs, to whom to report, and what form to use.
2. Your response to item no. 3 is inadequate since you do not address a requirement for evaluation of suppliers, consultants and contractors.

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 FDA 483 issued at the closure 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 the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

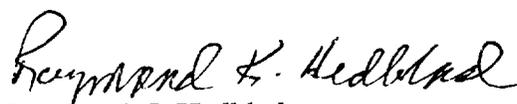
Federal agencies are advised of the issuance of all warning letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submission for devices to which the GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no request for Certificates for Products to 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 specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying system problems necessary to assure that similar violations will not recur. If corrective action cannot be taken within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be addressed to the attention of Joseph E. Hayes, Compliance Officer, Food and Drug Administration, 297 Plus Park Boulevard, Nashville, Tennessee 37217.

Sincerely,



Raymond K. Hedblad
Director, Nashville District

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Enclosures:

FDA Form 483
21 CFR Part 820