



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

HFI-35
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NOV 25 1998

WARNING LETTER
VIA EXPRESS

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Anthony P. Johnson
Managing Director
Ultramedic Ltd.
4G Wavertree Boulevard South
Liverpool, England L7 9PF

Dear Mr. Johnson:

During an inspection of your firm located in Liverpool, England, on September 28 - October 1, 1998, our investigator determined that your firm manufactures infusion pump analyzers, the IDA-4 and the IDA-2Plus. These analyzers are devices as defined by Section 201(h) of the Federal, Food, Drug, and Cosmetic Act (the Act).

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 manufacturing, packing, storage, or installation are not in conformance with the Quality System Regulation, as specified in Title 21, Code of Federal Regulation (CFR), Part 820, as follows:

1. Failure to establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit, as required by 21 CFR 820.198(a). For example, there is no written procedure for evaluating and handling complaints and for completing the complaint form.
2. Failure to review and evaluate all complaints to determine whether an investigation is necessary, as required by 21 CFR 820.198(b). For example, confirmed product defects on the IDA-4 and IDA-2Plus units received for service repair were not evaluated as complaints.
3. Failure to adequately investigate the cause of nonconformities relating to product, processes, and the quality system, as required by 21 CFR 820.100(a)(2). For example, your corrective and preventive actions did not include evaluating devices in commercial distribution after changing the position of the glass tubing on the IDA-4 transducer assembly board.
4. Failure to correct and prevent recurrence of non-conforming product and other quality problems, as required by 21 CFR 820.100(a)(3). For example:
 - a. Your corrective and preventive action procedure, B14, does not provide for control and action to be taken on devices not yet distributed that are suspected of having potential non-conformities; and

- b. Your corrective and preventive action procedure, B14 does not provide for evaluating products in commercial distribution, nor documenting justification of why this is not done.
5. Failure to adequately establish 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). For example, your procedure entitled “B4 Design Control” does not contain any of the elements listed above.

In addition, you need to reevaluate and modify the entire “B4 Design Control” procedure to include all elements of 21 CFR 820.30, Design Controls.

6. Failure to have an established protocol to validate computer software for its intended use when computers or automated data processing systems are used as part of production or the quality system, as required by 21 CFR 820.70(i). For example, there is no validation protocol for the validation study performed on the software of the IDA-4.
7. Failure to analyze service reports with appropriate statistical methodology in accordance with 21 CFR 820.100, as required by 21 CFR 820.200(b). For example, you do not monitor and trend confirmed product defects on the IDA-4 and IDA-2Plus’ returned for repair after the one year warranty period has expired.
8. Failure to approve changes by an individual in the same function or organization that performed the original review and approval, and failure to include the approval date and effective date on change records, as required by 21 CFR 820.40(b). For example, there has been no formal approval of changes made on the IDA-4, such as, repositioning of the glass tubing, and there are no approval and effective dates for these changes.
9. Failure to establish and maintain procedures to ensure that the device history records for each batch, lot, or unit are maintained to demonstrate that the device is manufactured in accordance with the device master record and the requirements of this part, as required by 21 CFR 820.184. For example, it was observed that you lack the above mentioned procedures.

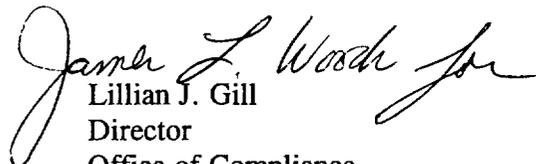
This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the form FDA 483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your firm’s manufacturing and quality assurance system. You are responsible for investigating and determining the causes of the violations identified by the Food and Drug Administration. 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.

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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. If documentation is not in English, please provide an English translation to facilitate our review. Please address your response and any questions to the Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Division of Enforcement II, General Hospital Devices Branch, HFZ-333, 2098 Gaither Road, Rockville, Maryland 20850, to the attention of Ms. Carolyn Niebauer.

Should you require any assistance in understanding the contents of this letter, do not hesitate to contact Ms. Leslie E. Dorsey at the letterhead address or at (301) 594-4618 or FAX (301)594-4638.

Sincerely yours,


Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health