



Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

April 6, 1998

**WARNING LETTER
FEDERAL EXPRESS**

Sang-Yong Lee, M.D.
Dr. Lee Co., Ltd.
415 SeokChon-Ri
Jongcheon-Myon, Seocheon-Gun
Chungnam 325-870
KOREA

Dear Dr. Lee:

During an inspection of your manufacturing facility by the United States Food and Drug Administration, from December 15-17, 1997, our investigator observed conditions at your manufacturing facility at the above address which are considered serious violations of the United States Federal Food, Drug, and Cosmetic Act (the Act). These violations were provided to you on the FDA 483 and are also discussed below. Further, we are in receipt of your response to the FDA 483 dated December 26, 1997, and the results of that review is also indicated below each charge as it applies.

The devices manufactured by your firm may be adulterated in accordance with section 501(h) of the Act because they are not manufactured in accordance with the Good Manufacturing Practice (GMP) regulation under Title 21, Code of Federal Regulations (FR), Part 820, as follows:

1. Failure to investigate the cause of nonconformities relating to product, process, and the quality system, as required by 21 CFR 820.100(a)(2). For example, your firm did not conduct failure investigations or determine the cause for the failures of the device.

The review of your December 26, 1997, response letter indicates that the corrective action appears to be adequate.

2. Failure to verify or validate the corrective and preventive action to assure that such action is effective and does not adversely affect the finished device, as required by 21 CFR 820.100(a)(4). For example, there was a problem causing the overlapping of the AVL and AVR signals resulting in incorrect QRS signals. The corrective action involved multiple software revisions, but there was no documented validation test procedure. Without the test results, it is impossible to ascertain failure causes, software changes, and the effectiveness of the corrective action.

The review of your December 26, 1997, response letter indicates that the corrective action is inadequate and the referenced Section 4.4 has not been provided.

3. Failure to establish changes to a specification, method, process, or procedure and approve changes, as required by 21 CFR 820.70(b). For example, there is no production change control procedure to control software changes.

A review of your letter of December 26, 1997, referenced procedures in section 4.4, but the documentation was not provided for review. Further, section 4.5.3 does not fully document the process to be undertaken. This response is inadequate.

4. Failure to document acceptance activities required by this part including the acceptance activities performed; the dates acceptance activities are performed; the results; the signature of the individual(s) conducting the acceptance activities; and, where appropriate, the equipment used, as required by 21 CFR 820.80(e). For example, records documenting initial rejects of the electronics components, such as analog, digital, interface boards, which were established as a result of the in-process and finished device tests were not kept.

The December 26, 1997, response references that procedures were developed in section 4.16, however, this procedure was not provided for review. This response, therefore, is inadequate.

5. Failure to establish and maintain procedures to control all documents that are required by this part; assure that changes to documents are reviewed and approved; and maintain records of changes to documents, including a description of the change, as required by 21 CFR 820.40(b). For example:
 - a. The production software release checklist for ECG Model 310A does not document who reviewed and approved the changes made to its operating software.

Your December 26, 1997, response indicates that the corrective action in section 4.5.3 may be adequate, but the referenced section 4.4 was not provided, therefore this response is inadequate.

- b. The burn-in test is no longer performed, but the final testing procedure, DRQG-10201, dated 11/19/97, was not revised to reflect this change.

The response in the December 26, 1997, letter appears to be adequate.

- c. There is no procedure to review and approve product change procedure documents and no date or signature of the approving official.

The December 26, 1997, response referenced procedures in section 4.4, but did not provide the documentation. The procedures in section 4.5.3 do not fully document the process to be undertaken, therefore the response is inadequate.

6. Failure to implement procedures for identifying with a control number each unit and documenting such identification in the Device History Record to facilitate corrective action, as required 21 CFR 820.65. For example, since device serial numbers were not identified, it is impossible to locate the exact testing records or to determine how the devices were manufactured and tested.

The review of the December 26, 1997, response indicates you have failed to address this issue.

7. Failure to maintain adequate complaint files and failure to adequately investigate complaints of device failures, as required by 21 CFR 820.198. For example, customer complaints concerning 7 faulty ECG-310B devices were not documented.

The review of the December 26, 1997, response indicates that the corrective action appears to be adequate.

8. Failure to maintain records of investigations that include any device identification and control number, as required by 21 CFR 820.198(e). For example the complaint files do not document the serial numbers and operating software versions for complaints.

The review of the December 26, 1997, response indicates that the corrective action appears to be adequate.

9. Failure to assure that sampling plans are written and based on a valid statistical rationale and ensure that sampling methods are adequate for their intended use and are documented, as required by 21 CFR 820.250(b). For example, 15 units were randomly pulled from a lot of 100 ECG units for the safety test, but the sampling size and method is not documented.

The December 26, 1997, response indicated MIL-STD-105 will be used as a reference for the sampling plan, but did not indicate which revision. Revision E is the latest revision of MIL-STD-105, however, in 1993 MIL-STD-105E was replaced by ANSI-Z1.4-1 "Sampling Procedures and Tables for Inspection by Attributes". This standard can be obtained from: American Society for Quality Control, 611 East Wisconsin Avenue, Milwaukee, Wisconsin 53202. Since a sampling plan has not yet been identified this response, therefore, is inadequate.

10. Failure to maintain device history records to demonstrate that the device is manufactured in accordance with the device master record and the requirements of this part. Identifying the software version would show that the device was manufactured in accordance with the device master record, as required by 21 CFR

820.184. For example, the final inspection records for the ECG devices do not document the operating software version.

This response appears to be adequate.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that all medical devices manufactured, distributed, held, and labeled by your firm are in compliance with the provisions of the Act.

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 the GMP deficiencies are reasonably related will be cleared until the violations have been corrected.

Given the serious nature of these violations of the Act, the Electrocardiograph, Model ECG-310A, may be detained without physical examination upon entry into the United States until these violations are satisfactorily corrected.

In order to remove the above stated devices from this detention, it will be necessary for you to provide a written response to the violations listed in this Warning Letter for our review. After we notify you that the response is adequate, it will be your responsibility to schedule another inspection of your facility. As soon as the inspection has taken place, the implementation of your corrections have been verified, and you are notified that your corrections are adequate, your devices may resume entry into this country.

Please notify this office, within 15 days of receipt of this letter of the specific actions you have taken to correct the noted violations. Please include any and all documentation in English to show that adequate correction has been achieved. In the case there will be future corrections, please provide an estimated date of correction and documentation showing plans for correction should be included with your response. Please address your response to:

Ms. Mary Ann Fitzgerald
Cardiovascular and Neurological Devices Branch
Division of Enforcement III
Office of Compliance
U.S. Food and Drug Administration
2098 Gaither Road
Rockville, Maryland 20850
U.S.A.

Should you require any assistance in understanding the contents of this letter, you may contact Ms. Fitzgerald at 301-594-4648, or you may write to her at the above address.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Lillian J. Gill". The signature is written in black ink and is positioned above the typed name.

Lillian J. Gill

Director

Office of Compliance

Center for Devices and Radiological Health