DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

Chicago District
550 West Jackson Blvd., 15th Floor
Chicago, Illinois 60661
Telephone: 312-353-5863

December 8, 2006

WARNING LETTER
CHI-2-07

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. James P. Fee, Jr., President
MRL, Inc., a Welch Allyn Company
1000 Asbury Drive Suite 17
Buffalo Grove, IL 60089

Dear Mr. Fee:

United States Food and Drug Administration (FDA) investigators conducted an inspection of your firm located in Buffalo Grove, IL, from May 22 through July 20, 2006. The investigators determined that your firm manufactures automatic external defibrillators. Under Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. 321(h)], these products are devices because they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or are intended to affect the structure or function of the body.

This inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act [21 U.S.C. 351(h)], in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the current Good Manufacturing Practice (cGMP) requirements of the Quality System (QS) regulation found at Title 21, Code of Federal Regulations (CFR), Part 820.

We received three monthly responses from Kevin Cahill, Executive Vice President, and Chris Horacek, Office of the President, dated August 11, 2006, September 14, 2006 and October 31, 2006. The responses were directed to our investigators' observations noted on the FDA 483, Inspectional Observations, that was issued to you. We address your responses below, after the description of the deficiencies. These deficiencies include, but are not limited to, the following:

1. Failure to establish and maintain procedures for implementing corrective and preventive actions. The procedures must include verifying or validating the corrective and preventive actions to ensure that such actions are effective and do not adversely affect the finished device, as required by 21 CFR 820.100(a)(4). For example, the corrective action of adding [redacted] to the [redacted] socket during manufacturing and servicing of PIC 50 and AED 20 has not been verified or validated as to be effective in preventing an unacceptable delay or prevent the delivery of therapy.

Your response to FDA-483 Observation # 1 appears to be adequate.

2. Failure as a manufacturer to establish and maintain procedures for verification of your device's design. Design verification must confirm that the design output meets the design input requirements. The results of the design verification, including identification of the design, methods, the date, and the individuals performing the verification, must be documented in the device history file, as required by 21 CFR 820.30(f). For example, the vibration test method used in the design verification was not the test listed in the product specifications.

We have reviewed your response to FDA-483 Observation # 2 and have concluded that it is inadequate. You have responded only to the example described in the FDA-483. This example demonstrates to us that your firm needs to conduct a global review of other specifications and products.

3. Failure to maintain complaint files. As a manufacturer you must establish and maintain procedures for receiving, reviewing, and evaluating complaints for a formally designated unit. Such procedures must ensure that any complaint involving the possible failure of a device, labeling, or packaging to meet any of its specification must be reviewed, evaluated and investigated, unless such investigation has already been performed for a similar complaint and another investigation is not necessary, as required by 21 CFR 820.198(c). For example, a complaint involving a PIC 50 was not investigated or a follow-up was not made to find out if devices treated with [redacted], a terminal cleaner /protectant designed to help prevent corrosion from forming on metal to metal contacts, was affected by corrosion.

Your response to FDA-483 Observation # 3 appears to be adequate.

4. Medical Device Reporting (MDR): Failure to maintain complaint files. As a manufacturer you must establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit. Such procedures must ensure that any complaint that represents an event which must be reported to FDA under 21 CFR 803 will be investigated by a designated individual and will be maintained in a separate portion of the complaint files or otherwise clearly identified, as required by 21 CFR 820.198(d). For example, a complaint involving an MDR reportable death event was reported to your firm. The complaint about the PIC 50 device involved in that complaint was received on 6/25/04, and a formal complaint investigation was not initiated until 10/08/04, nearly four months later. FDA sent your firm a letter on 8/20/2004 requesting additional information concerning the referenced incident. The FDA letter gave a time frame of 45 days of receipt of the letter to respond. Your firm's response letter was dated 10/14/04 which was 55 days from the receipt of the FDA letter, making it 10 days beyond the requested response date.

We have reviewed your response FDA-483 Observation # 5 and have concluded that it is inadequate because of your failure to follow your CAPA 455Q, which addresses the filing of late MDRs. In your response, your effectiveness checks covered only 3 months, not the 6 months time frame stated in your CAPA 455Q.

5. Failure to have established nonconformity review and disposition of manufactured devices. Each manufacturer must establish and maintain procedures that define the responsibility for review and authority for the disposition of nonconforming product. The procedures must set forth the review and disposition process. Documentation must include the justification for use of nonconforming product and signature of individuals authorizing the use, as required by 21 CFR 820.90(b)(1). For example, conclusions were documented on a complaint investigation by a quality consultant who had neither the responsibility, evidence, background training, or experience to make such a conclusion.

Your response to FDA-483 Observation # 7 appears to be adequate.

6. Failure to establish and maintain instructions and procedures for performing and verifying that servicing meets the specified requirements, as required by 21 CFR 820.200(c). Each manufacturer who receives a service report that represents an event which must be reported to FDA under 21 CFR 803, must automatically consider the report a complaint and must process it in accordance with the requirements of 820.198. For example, two repair orders, R24951 (dated 02/07/2006, AED 20 device, S/N [redacted]) and R23948 (dated 03/07/2006, AED 20 device, S/N [redacted]), were confirmed to have "Defib Comm Fail". These repair orders were not evaluated to determine if they were MDR reportable events at the time of servicing, even though similar failure modes have been reported by your firm in other MDR reports.

Your response to FDA-483 Observation # 9 appears to be adequate.

7. Failure to establish and maintain instructions and procedures for performing and verifying that servicing meets the specified requirements, as required by 21 CFR 820.200(a). Each manufacturer must establish and maintain instructions and procedures for performing and verifying that servicing meets specified requirements. For example, service procedures were not implemented for MDR 1418729-2004-00009. The date and signature of the person who decided to complete this form were not documented and the signature of the person who decided not to complete an MDR reportable event record in a repair order number R21591 was not documented.

Your response to FDA-483 Observation # 10 appears to be adequate.

8. Failure to investigate the cause of nonconformities relating to product, processes, and the quality system, as required by 21 CFR 820.100(a)(2). For example, the following procedures, Complaint Handling, Defect Tracking and Trending, Nonconforming Material and Repair of Equipment, do not include procedures for performing failure investigations.

Your response to FDA-483 Observation # 11 appears to be adequate.

9. Failure to analyze 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). For example, procedures for Corrective and Preventive Action, Complaint Handling, Tracking and Trending, and Statistical Techniques and Analysis of Data, do not contain a list of maintained databases for collecting failure data or the requirements for how those databases should be maintained and evaluated.

We have reviewed your response to FDA-483 Observation # 12 and conclude that the plan was adequate, but without completion of the databases we have no assurance that its implementation will be adequate.

10. Failure to have production and process controls for automated processes, as required by 21 CFR 820.70(i). when computers or automated data processing systems are used as part of production or the quality system. A manufacturer is required to validate computer software for its intended use according to an established protocol. For example, databases that are maintained for data analysis and other tracking and trending functions, including complaint and services access databases, have not been validated for their intended use.

We have reviewed your response to FDA-483 Observation # 13 and conclude that it is inadequate because, without completion of the validation, we have no assurance that it will be adequate.

11. Failure to establish and maintain instructions and procedures for performing and verifying that servicing meets the specified requirements, as required by 21 CFR 820.200(b). Each manufacturer must analyze service reports with appropriate statistical methodology in accordance with Section 820.100. For example, your quality group reviews narrative summaries of service reports every two weeks, but the data is not tracked and trended according to a statistical method.

We have reviewed your response to FDA-483 Observation # 14 and have concluded that it is inadequate because it is not clear if the old data is going to be merged in the new validated database when it becomes available.

12. Failure as a manufacturer to establish procedures for identifying training needs and to ensure that all personnel are trained to adequately perform their assigned responsibilities. Training must be documented, as required by 21 CFR 820.25(b). For example, the current Complaint Coordinator was documented as an initiator and evaluator for complaint closure before being trained for that job. Also, the current Service Manager has been working at the company for approximately 12 years, and that employee has never been trained in the most current Document Control procedures. Also, the current Material Manager has no training documentation that provides a description of the verification method used to measure training effectiveness for the following subjects: returned goods to stock; corrective and preventive action (CAPA); FORMS; and, Operations Standard Operating Procedures.

Your response to FDA-483 Observations # 16 and # 17 appears to be adequate.

13. Failure to have control of nonconforming manufactured product. Each manufacturer must establish and maintain procedures to control product that does not conform to specified requirements. The procedures must address the identification, documentation, evaluation, segregation, and disposition of nonconforming product, as required by 21 CFR 820.90(a). For example, we determined that, for nonconforming material reports for returning components to vendors for investigation, the supplier corrective action response Section of the nonconforming report was not always completed.

We have reviewed your response to FDA-483 Observation # 18 and have concluded that it is inadequate because, while the actual Supplier's Corrective Action Request (SCAR) has been completed, two other corrective actions, including evaluation of the SCARs dating back to April 2003, and review of SOP's for appropriateness, have not been completed.

14. Failure to maintain complaint files. As described above, you must establish and maintain procedures for receiving, reviewing, and evaluating complaints for a formally designated unit. Such procedures must ensure that: all complaints are processed in a uniform and timely manner; oral complaints are documented upon receipt; and complaints are evaluated to determine whether they represent an event which is required to be reported under 21 CFR 803, as required by 21 CFR 820.198(a). For example, the current compliant handling procedure does not reference a Failure Investigation SOP as an associated document and does not address when and how to reply to the complainant when an investigation is conducted. Also, your complaint # 2005011181 does not have the MDR number filled in and the investigation required field was not checked. Complaint # 20510271 did not have the corrective and preventive action (CAPA) information.

Your response to FDA-483 Observations # 19 and # 25 appears to be adequate.

15. Failure to implement and record changes in methods and procedures needed to correct and prevent identified quality problems, as required under 21 CFR 820.100(a)(5). For example, a corrective action plan was created to change the method used in the service department to store components that were removed from devices. Changes were recorded, but the written procedures were not updated with current changes.

Your response to FDA-483 Observation # 21 appears to be adequate.

16. Failure to follow document controls requirements. Each manufacturer must establish and maintain procedures to control all documents that are required by 21 CFR 820.40. For example, after the original signed and initiated Corrective and Preventive action (CAPA) 440C document was lost, a rewritten CAPA 440C document was not filed until nearly one year later.

We have reviewed your response for FDA-483 Observation # 22 and have concluded that it is inadequate because the required corrective and preventive action has not been completed.

17. Failure to document corrective and preventive action activities and their results, as required by 21 CFR 820.100(b). For example, the rewritten CAPA 440C form was incomplete. Two things were missing. The first was that the type of action was not checked as corrective or preventive action. The second was that verification or validation is required and no documentation was attached or referenced to CAPA 440C.

We have reviewed your response for FDA-483 Observation # 23 and have concluded that it is inadequate because the new rewritten CAPA 440C was incomplete, and no referenced documentation was attached for review to indicate verification and validation was completed.

18. Failure to identify the actions needed to correct and prevent recurrence of nonconforming product and other quality problems as required in 21 CFR 820.100(a)(3). For example, your firm's rewritten CAPA 440C did not address quality problems identified in complaint #200510271. That complaint involved product lost in the material review board's area, but CAPA 440C addresses product stored in the service department. Also, the rewritten CAPA 440C references the wrong complaint number, not #200510271.

We have reviewed your response for FDA-483 Observation # 24 and have concluded that it is inadequate because your firm had already determined that a CAPA was warranted. Your firm has not appropriately documented the corrections taken in response to the issues that arose during this complaint investigation.

Our inspection also revealed that your automatic external defibrillator (AED 20) and portable intensive care system (PIC 50) devices are misbranded under Section 502(t)(2) of the Act, 21 U.S.C. 352(t)(2), in that your firm failed to furnish material or information respecting the device that is required by or under Section 519 of the Act, 21 U.S.C. 360i, and 21 CFR Part 803 – the Medical Device Reporting (MDR) regulation. Significant deviations include, but are not limited to, the following:

19. Failure to fulfill manufacturer's requirements. You must report to FDA no later than 30 days after the day that you receive or otherwise become aware of information, from any source, that reasonably suggests that a device that you market may have caused or contributed to a death or serious injury, as required by 21 CFR 803.50(a)(1). For instance, as an example of non-compliance, an MDR report was not submitted to FDA within 30 days after your firm became aware of information that a PIC 50 had caused or contributed to a death of a patient.

We have reviewed your response to FDA-483 Observation # 4 and have concluded that it is inadequate because your failure to follow your CAPA 455Q, which addresses the filing of late MDRs. In your responses your effectiveness checks covered only 3 months, not the 6 months time frame stated in your CAPA 455Q.

20. MDR reporting failure. When you obtained information required under the MDR regulation, you did not provide it timely because it was not known or was not available when you submitted the initial report. You are required to submit the supplemental information to FDA within one month of the day that you receive this information on a supplemental or follow up report, as required by 21 CFR 803.56. For example, the supplemental report for MDR 1418729-2005-00186, dated 10/27/2005, involving a patient's death, was submitted to FDA on 3/23/2006, well after the one month time frame. You also failed to submit within one month a supplemental report for MDR 1418729-2005-00106 that should have included the complaint investigation information not provided in the original MDR.

We have reviewed your response FDA-483 Observation # 6 and have concluded that it is inadequate because your failure to follow your CAPA 455Q, which addresses the filing of late MDRs. In your responses, your effectiveness checks covered only 3 months, not the 6 months time frame stated in your CAPA 455Q.

21. Failure as a user facility, importer or manufacturer. You must develop, maintain, and implement written MDR procedures for internal systems that provide for timely and effective identification, communication, and evaluation of events that may be subject to MDR requirements, as required by 21 CFR 803.17. For example, two different MDR incidences, one with a PIC 50 device and the other with a AED-20, were given the same MDR number and submitted to the FDA. Also, your Quality system procedures do not address the manner of attempting to acquire patient identification information for the Medwatch form.

Your response to FDA-483 Observation # 15 appears to be adequate.

22. Failure in your responsibility for obtaining and submitting to FDA information that is incomplete or missing from reports submitted by user facilities, importers, and other initial reporters, as required by 21 CFR 803.50(b)(2). For example, three MDR reports did not include patient information and no steps were documented as taken to assure that such information would be attempted to be acquired.

Your response to FDA-483 Observation # 20 appears to be adequate.

We will not be able to verify fully the sufficiency of all your responses until the next inspection. As you have promised, however, please continue to provide updates, if applicable, on the status of corrective actions you have taken.

You should take prompt action to correct the violations addressed in this letter. 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 money penalties. Also, 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, premarket approval applications for Class III devices to which the Quality System regulation deviations are reasonably related will not be approved until the violations have been corrected. Requests for Certificates to Foreign Governments will not be granted until the violations related to the subject devices have been corrected.

Please notify this office in writing within 15 working days from the date you receive this letter of the specific steps you have taken to correct the noted violations, including an explanation of how you plan to prevent these violations, or similar violations, from occurring again. Include documentation of the corrective action you have taken. If your planned corrections will occur over time, please include a timetable for implementation of those corrections. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to: Matthew J. Sienko Compliance Officer at 550 West Jackson Blvd, 15th Floor, Chicago, Illinois 60661. If you have any questions about the content of this letter please contact Mr. Sienko at (312) 596-4213.

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your facility. It is your responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violations noted in this letter and in the Inspectional Observations, Form FDA 483, issued at the closeout of the inspection

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Sincerely,

Scott J. MacIntire
District Director

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