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June 8, 2000

VIA FEDERAL EXPRESS

Robert J. Tennison
President
Hill-Rom, Inc.
1069 State Route 46 East
Batesville, IN 47006-9167

Warning Letter
(00-ATL-43)

Dear Mr. Tennison:

During an inspection of your firm located in Cary, NC on 3/22-31/00, Atlanta District Investigators E. Harold Blackwood and Claudette D. Brooks determined that your firm manufactures and distributes obstetrical patient data management systems. These products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act). The investigators documented significant deviations from the Quality System Regulation (QSR), as set forth in Title 21 Code of Federal Regulations (21 CFR), Part 820. These deviations cause your devices to be adulterated within the meaning of Section 501(h) of the Act.

You have failed to establish an organizational structure which includes provisions for responsibility, authority, and resources. You did not have permanently assigned personnel in the top three key positions of Vice President, Site Manager and Business Unit Manager. Your organizational structure did not allow for personnel with the assigned authority and responsibility to make corrections to problems identified in the quality system. You did not have a sufficient number of trained personnel to evaluate customer complaints and service calls.

Your firm failed to have an effective quality assurance unit/function. Management with executive responsibility has not ensured that the written quality policy is understood and followed. Management reviews were not being conducted with sufficient frequency to evaluate the suitability and effectiveness of the Quality System. Management reviews were scheduled biweekly, but only two reviews were held on 12/22/99 and 3/00.

You failed to evaluate suppliers of components and other materials used to assemble the WatchChild™ device. You had not documented your decisions to use the approved vendors on the approved vendor list. While you have a written procedure for supplier certification and decertification, it was not being followed. The type and extent of control to be exercised over the suppliers has not been defined.

You failed to perform incoming inspection of your components to verify that they conform to your specifications. You also failed to perform in-process and final inspection of components (software)

manufactured at your firm. The acting operations manager was not familiar with the written procedures for receiving, in-process and finished device acceptance. He indicated that the firm never followed these procedures.

You failed to review and evaluate all complaints and service calls received to determine whether the complaint/service record represents an event, which is required to be reported to FDA under the Medical Device Reporting (MDR) regulation, (21 CFR) Part 803. You do not have a complaint handling unit which is responsible for reviewing and evaluating complaints/service records to determine MDR reportability.

You failed to appropriately review service reports/calls to determine if they should actually be recorded and investigated as complaints. You failed to conduct follow-up investigations to determine root cause of the failures. At the time of the inspection, complaints and service records were observed in several cardboard boxes still waiting to be reviewed. Between October 1999 and March 2000, you received approximately 5,374 calls.

You failed to take appropriate corrective action for significant product and quality problems identified, for example:

- a) A corrective action requiring field modification of WatchChild™ device was identified in October 1999. This action would have reduced the likelihood of devices failing to transmit data. (DAS labeling). You have not implemented this modification. You continued to receive complaints relevant to this problem.
- b) Complaint dated 1/13/00 in which you determined that the wall plate port was never connected and data was lost because the nurse did not know that the port in which the fetal monitor was connected was inactive. You identified the need for corrective action to prevent mistakes of plugging the fetal monitors into dead ports, however no corrective action was implemented.
- c) Customer correspondences and call log entries indicate that there are many unresolved performance problems for the WatchChild™ system such as fetal strip data losses, alarm failures, system freezing, blank screens, and DAS failures.
- d) [REDACTED] terminals have smoked or caught fire in four hospitals since 1/17/00.

You failed to have a Device Master Record for the WatchChild™ device. Records of the WatchChild™ software validation were incomplete.

You failed to maintain adequate and complete installation records. You failed to calibrate equipment (Fluke meters) used by the installers. Review of installation records and service calls revealed several installations to have non-supported monitors connected to the WatchChild™ System.

Additionally, the above stated inspection revealed your devices are misbranded within the meaning of Section 502 (t)(2) of the Act, in that your firm failed to submit information to the FDA as required by the Medical Device Reporting (MDR) regulation, as specified in 21 CFR Part 803. Specifically, you failed to submit MDR reports to FDA after receiving information, which reasonably suggested that one of your commercially distributed devices had malfunctioned and may cause or contribute to death or serious injury if the malfunction were to recur. MDR malfunction reports are required for these incidents:

1. Incident report dated 2/3/00 in which the alarms were not alarming when baby was in distress.
2. Incident report dated 1/5/00 in which the alarms were not working when there was a problem with a baby.
3. Incident report dated 9/9/99 in which the alarms were not working.

In the above 3 incidents, your firm failed to adequately investigate these incidents and evaluate the cause. Your firm also failed to document its deliberations and decision-making processes used to determine if a device-related death, serious injury, or malfunction was reportable/not reportable as required by 803.18(b)(1)(i).

Written MDR reports for each of the above listed incidents are to be submitted within 15 working days of receipt of this letter. The MDR reports should reference this Warning Letter and be directed to:

Victoria Schmid
Food and Drug Administration
Reporting Systems Monitoring Branch (HFZ-533)
Office of Surveillance and Biometrics
Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, Maryland 20850

There were additional incidents where you failed to adequately investigate and evaluate the cause of the events as required by 803.50(b)(2). In addition, your firm failed to document its deliberation and decision making processes used to determine if a device related death, serious injury, or malfunction was reportable/not reportable. For example:

1. Incident report dated 1/13/00 in which there was a reported baby death. You failed to investigate the circumstances and possible cause of the baby's death.
2. Incident report dated 11/19/99 in which there was a reported maternal death. You failed to investigate and/or document the maternal death.
3. Incident report dated 8/20/99 in which there was a reported patient death during delivery. You failed to investigate and/or document this report of death.

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, Inspectional Observations (copy enclosed) issued at the closeout 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.

Following the 9/99 inspection of your firm while it was located in Costa Mesa, CA, Mr. Sudhir Pahwa, Vice President and General Manager promised corrective action via letter dated October 15, 1999. However, our inspection of your Cary, NC facility revealed that the majority of the QSR deviations noted during this inspection were also noted during the 9/99 inspection of your firm.

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 devices to which the Quality System/GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates For 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 FDA 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 systems problems necessary to assure that similar violations will not recur. If corrective actions cannot be completed within fifteen working days, state the reason for the delay and the time within which corrections will be completed.

We acknowledge receipt of a letter dated 5/11/00 from Mr. Gary L. Moore, Vice President/General Manager. We are currently reviewing your response letter. You can refer to your 5/11/00 response in your answer to this Warning Letter. Your response should be sent to Serene A. Kimel, Compliance Officer at the address noted in the letterhead.

Sincerely,



Ballard H. Graham, Director
Atlanta District

Enclosure

Cc: Mr. Gary L. Moore, Vice President/General Manager
11000 Regency Parkway, West Tower, Suite 205
Cary, NC 27511