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Food and Drug Administration
2098 Gaither Road
Rockville, Maryland 20850

MAY 3 2001

WARNING LETTER

VIA FEDERAL EXPRESS

Mr. Hans Bergh
President
Permobil AB
Box 120/Årvältsvägen 10
S-861 23 Timrå, Sweden

Dear Mr. Bergh:

We are writing to you because on February 26-27, 2001, and March 2, 2001, an investigator from the Food and Drug Administration (FDA) collected information that revealed serious regulatory problems involving your powered wheelchairs.

Under a United States Federal law, the Federal Food, Drug, and Cosmetic Act (the Act), these products are considered medical devices because they are used to diagnose or treat a medical condition or to affect the structure or function of the body (Section 201(h) of the Act).

The above-stated inspection revealed that the methods used in, or the facilities or controls used for, manufacturing, packing, storage, or installation of these devices are not in conformance with the Quality System Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820. In legal terms, the products are adulterated within the meaning of section 501(h) of the Act, as follows:

- 1. Failure to establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system as required by 21 CFR 820.22.** For example, procedures for conducting quality audits were not implemented or followed in that the procedures for conducting the quality audit were no longer part of the documented system and the QA-manager stated that quality system audits had not been performed for at least 1 year and none were planned.

Your written response dated March 14, 2001, states that the quality audit procedure, used until 1994, will be re-implemented in the quality system and that internal trained auditors will perform the audit of the operational effectiveness. An internal auditor will perform the audit of the quality system. Training of internal auditor starts May 2001. First external audit of the quality system is planned for October 2001.

This response is not considered adequate because a copy of the new procedures was not submitted and there is no documentation that they have been implemented.

- 2. Failure to establish and maintain complaint procedures to determine whether a complaint represents an event which is required to be reported to FDA as required by 21 CFR 820.198(a)(3).** For example, four events—one related to malfunction, two related to injuries and one related to death—have not been evaluated for MDR reportability.

Your written response, dated March 14, 2001, states that the procedures for non-conformity and customer complaints comply with the requirements in MDD 93/42 and will be updated to show that they better cover the MDR requirement, and will be effective before March, 2001.

This response is not considered adequate since a copy of the new procedures was not submitted and there is no documentation indicating that they have been implemented.

- 3. Failure to establish and maintain procedures to ensure that the design requirements relating to a device are appropriate and address the intended use of the device, including the needs of the user and patient.** For example, there is no requirement for establishing a design input, in accordance with 21 CFR 820.30(c).

During the inspection the firm showed a draft document with a detailed flow diagram intended to document the design control requirements and the different phases and it was indicated that the document would be issued as a part of the quality system.

This response is not considered adequate because a final design control plan has not been submitted, nor is there evidence that it has been implemented.

- 4. Failure to establish and maintain procedures for defining and documenting design output in terms that allow an adequate evaluation of conformance to design input requirements in accordance with 21 CFR 820.30(d).** For example, the design outputs for the Chairman 2k device currently shipped to the U.S., that are essential for the performance of the device, are not specifically identified.

Your written response of March 14, 2001, states that a new design plan includes the procedure for design control.

This response is not considered adequate because a copy of the new design plan was not submitted and no documentation of its implementation was provided.

- 5. Failure to establish and maintain procedures to ensure that formal documented reviews of the design results are planned and conducted at appropriate stages of the device's design development in accordance with 21 CFR 820.30(e).** For example, there is no requirement for establishing the design review.

Your written response of March 14, 2001, states that a new design plan includes a procedure for design controls.

This response is not considered adequate because a copy of the new design plan was not submitted and no documentation of its implementation was provided.

6. Failure to establish and maintain procedures for validating the device design in accordance with 21 CFR 820.30(g). For example:

- a. There is no requirement for performing a risk analysis.
- b. In the risk analysis for the Chairman 2k device, three risks remain to be closed.
- c. The edition 2 of the Chairman 2k Operator's Manual to close one of the three above risks was not formally approved.
- d. The test report for documenting compliance with EMC requirements for the Chairman 2k device was not available.
- e. Validation performed for the Chairman 2k device under actual or simulated use conditions was not documented.

Your written response of March 14, 2001, states that a new design plan includes a procedure for design controls.

This response is not considered adequate because a copy of the new design plan was not submitted and no documentation of its implementation was provided.

7. Failure to maintain a device master record (DMR) in accordance with 21 CFR 820.181. For example, the DMR has not been prepared for the Chairman 2k device.

Your written response of March 14, 2001, states that there is a procedure in place to approve design changes.

This response is not considered adequate because a copy of the procedure was not submitted and no documentation of its implementation was provided.

8. Failure by management with executive responsibility to ensure that the quality policy is understood, implemented, and maintained at all levels of the organization as required by 21 CFR 820.20(a). For example, management with executive responsibility has not ensured that an adequate and effective quality system has been fully implemented and maintained at all levels of the organization. Specifically, this applies in the areas of quality audits, MDR reporting, and design controls.

Page 4 - Mr. Hans Bergh, President

Your written response, dated March 14, 2001, indicated that a number of procedures are under development to address this issue.

Your response is not considered adequate because you have not submitted the procedures nor documentation that they have been implemented (see previous comments).

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 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.

We acknowledge that you have submitted to this office a response, dated March 14, 2001, concerning our investigator's observations noted on the form FDA 483. We have reviewed your response and concluded that it is inadequate. An evaluation of specific responses is entered after each one of the deviations listed above.

You should take prompt action to correct any manufacturing or quality systems deviations identified by your internal audits. Failure to promptly correct these deviations may be identified in a follow-up inspection, and may result in the detention of your device(s) without physical examination upon entry into the United States.

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. Also, no requests for Certificates for Products for Export will be approved until the violations related to the subject devices have been corrected.

Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations. Include 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 action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. If the documentation is not in English, please provide a translation to facilitate our review.

Page 5 - Mr. Hans Bergh, President

Your response should be sent to:

James W. Eisele, Consumer Safety Officer
Office of Compliance
Division of Enforcement III (HFZ-343)
Center for Devices and Radiological Health
2094 Gaither Rd.
Rockville, MD 20850

If you have any questions about the contents of this letter, please contact Mr. Eisele at the above address or at (301) 594-4659, or fax (301) 594-4672. You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers Assistance at (301) 443-6597, or through the Internet at <http://www.fda.gov>.

Sincerely yours,



Larry D. Spears
Acting Director
Office of Compliance
Center for Devices and
Radiological Health