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Food and Drug Administration  
Center for Devices and  
Radiological Health  
2098 Gaither Road  
Rockville, MD 20850

**WARNING LETTER**  
**VIA EXPRESS**

NOV 5 2001

Mr. Geoff Hogg  
Quality Assurance Manager  
ARJO, Ltd.  
St. Catherine Street  
Gloucester, GL1 2SL, UK

Dear Mr. Hogg:

During an inspection of your firm located in Gloucester, United Kingdom on June 25-28, 2001, our investigator determined that your firm manufactures patient lift devices and bathing systems. These products are devices as defined by Section 201(h) of the Federal, Food, Drug, and Cosmetic Act (the Act).

We acknowledge receipt of your July 17 and September 6, 2001 responses to the FDA 483 issued to you at the conclusion of your inspection. We have reviewed your responses and incorporated the results of our review below.

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 adequately establish with a high degree of assurance a process which cannot be verified by subsequent inspection and test, as required by 21 CFR 820.75(a). For example:
  - a. A review of the washing validation tests [REDACTED] performed to verify slings can withstand [REDACTED] washes in a [REDACTED] low temperature wash cycle is incomplete in that the following deficiencies are noted:
    1. Only one sling of a particular design is tested at a high [REDACTED] and low [REDACTED] temperature. In addition, you have tested two other sling designs: the MAA-2000-L standard four point sling and the MAA4031-M four point toileting sling. However, you tested the MAA4031-M sling at a low temperature [REDACTED], but not at a high temperature. How can you be assured that all slings can withstand the washing temperature [REDACTED] indicated in your washing instructions.
    2. No test data was available to assure that temperature and [REDACTED] concentration specification requirements are met.
    3. No information was available which defines the composition of the test detergent used.

**Your response to this observation appears adequate; however, please clarify why the washing validation for the slings states that the slings are put through both a chemical and water wash, but the washing instructions for the user only indicate that a water wash is necessary.**

- b. A review of validation test data for the Chorus Patient Lift, which was performed to establish a ten year shelf-life for this device lacks the following:
  1. No defined/approved protocol exists, which defines the testing to be conducted and the acceptance criteria required for acceptance.
  2. No data was available, which identified test instrument of usage or whether those instruments were calibrated.

**Your response to this observation appears adequate in that you have identified whether the test instruments of usage have been calibrated; however, please be advised that you still need to meet the requirements specified under 21 CFR 820.72(b).**

2. Failure to document the equipment identification, calibration dates, the individual performing each calibration, and the next calibration date, as required by 21 CFR 72(b)(2). For example, no documentation currently exists on the daily calibration checks performed on the [REDACTED] meter used to verify the thickness of the [REDACTED] coating on component parts.

**Your response to this observation appears to be adequate.**

3. Failure to adequately establish procedures for finished device acceptance to ensure that each production run, lot, or batch of finished devices meets acceptance criteria, as required by 21 CFR 820.80(d). For example, load testing performed is a dead weight test (vertical stress), but fails to evaluate what effect lateral forces (horizontal stress) may have on slings and attachment clips, as would be experienced during patient transport.

**Your response to this observation appears to be adequate.**

In addition to the above GMP observations, your devices are misbranded within the meaning of section 502(t)(2) for failing to report the following Medical Device Reports of Corrections and Removals promulgated under section 519 of the Act; and for failing to report medical device reports (MDRs) as follows:

### **Medical Device Reports**

1. Failure to report within 30 days of receiving or becoming aware of information, from any source, that reasonably suggests that a device marketed by the manufacturer has malfunctioned and such device or similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur, as required by 21 CFR 803.50(a)(2). For example, you failed to submit an MDR for product complaint 084/00 dated April 27, 2000, which revealed a device malfunction in which a sling clip breakage occurred while lifting a patient.

**Your response did not address this cite.**

### **Corrections and Removals**

2. Failure to submit a written report to FDA of any correction or removal of a device to reduce a risk to health posed by the device, as required by 21 CFR 806.10(a)(1). For example, alignment arrows were installed on the Marisa Patient Lifts to ensure that users correctly locate the lift arm onto the carriage, and thus prevent possible patient injury.

**Your response did not address this cite.**

In addition, please address the following:

1. A safety notice was issued from the Medical Device Agency warning users of the potential danger to the attachment clips of the slings when the slings are subjected to mechanical pressure or rolling to remove water during the laundering process. Was this safety notice or any other notification of the problem issued in the United States?
2. The labeling for your slings specifies that the life expectancy is two years; however, the labeling for the patient lifts does not specify a life expectancy, which you indicate is 10 years. How does the user know when to replace their patient lift? It is also recommended that service contracts be put into place with your customers. This will ensure that the lifts get the proper servicing at the proper times and that the lifts and parts get replaced as necessary.
3. The life expectancy tests that you performed for your patient lifts failed to account for environmental conditions that the lift would be exposed to during real life situations (cleaning, disinfection, moisture ingress, temperature, etc.), which could possibly lead to pin corrosion and possible failure. Please explain.

**Your response did not address the above three concerns.**

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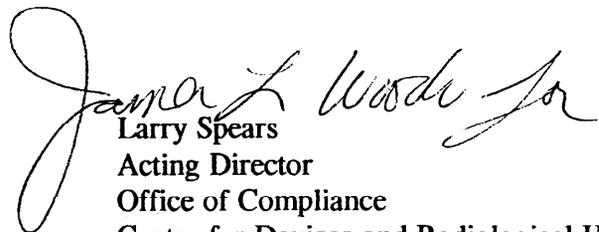
This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the form FDA 483 issued at the conclusion of the inspection may be 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.

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. Caster at the letterhead address or at 301.594.4618 or FAX 301.594.4638.

Sincerely yours,



Larry Spears  
Acting Director  
Office of Compliance

Center for Devices and Radiological Health