U.S. Food and Drug Administration

Inspections, Compliance, Enforcement, and Criminal Investigations

Medical Compression Systems 10/21/11

Department of Health and Human Services

Public Health Service
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

October 27, 2011

WARNING LETTER

VIA UNITED PARCEL SERVICE

Adi Dagan
Chief Executive Officer
Medical Compression System (DBN) Ltd.
2 Hailan St.
P.O. Box 75
Or-Akiva 30600, Israel

Dear Mr. Dagan:

During an inspection of your firm located in Or-Akivaon June 20, 2011, through June 23, 2011, an investigator from the United States Food and Drug Administration (FDA) determined that your firm manufactures the ActiveCare DVT and the ActiveCare + SFT. 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)), ir 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 requirements of the Quality System regulation found at Title 21, Code of Federal Regulations (CFR), Part 820.

We received a response from your firm dated July 12, 2011, concerning our investigator's observations noted on the Form FDA 483 (FDA 483), List of Inspectional Observations that was issued to your firm. We address this response below, in relation to each of the noted violations. These violations include, but are not limited to, the following:

1. Failure to establish and maintain adequate procedures for the identification, documentation, validation, or where appropriate, verification, review and approval of design changes before their implementation, as required by 21 CFR 820.30(i). For example: the device design was revised to include an **(b)(4)** for both the ActiveCare DVT and ActiveCare+SFT devices. Your firm's design validation report No.71365539, Safety Technical Report OVP, includes design verification test results where the device was tested a **(b)(4)** but does not appear to include testing of production units under actual or simulated conditions as indicated in your Design Verification and Validation procedure referenced in your Design Changes Procedure.

The adequacy of the response cannot be determined at this time. Your firm provided documentation for a retrospective analysis an a research and development report based on previous data obtained from **(b)(4)** as well as a plan for implementation. However, your firm did not provide a copy of the design master validation or documentation of the systemic corrective action.

2. Failure to adequately review, evaluate, and investigate complaints involving the possible failure of a device to meet any of its specifications, as required by 21 CFR 820.198(c). For example: Complaint No. 09013, dated 07/14/09, describes an event where **(b)(4)** and attributed the failure to **(b)(4)**. Complaint No.09025, dated 01/11/09, states that the **(b)(4).** Your firm provided powe supply replacements for both occurrences. However, your firm did not conduct an investigation to determine whether the **(b)(4)** associated with the unit was faulty and did not cause the units **(b)(4).**

The adequacy of the response cannot be determined at this time. Your firm opened CAPA No. 141 to address the need to investigate complaints received. Per this CAPA your firm revised the Complaint Handling procedure, R-QAP014-2, the complaint investigation form, and the Product Experience Form. However, documentation for the implementation of these changes at your firm and distribution level was not provided.

3. Failure to establish and maintain adequate procedures to ensure all complaints are processed in a uniform and timely manner, as required by 21 CFR 820.198(a)(1). For example: Section 5.1 of document R-QAP-14-2-R07, titled Handling Complaints, states **(b)(4).** However, complaints numbers CC1022, CC1023, and CC1029, were created on 1/23/2011, 3 months after the complaint dat and on product receipt date 10/11/2010 and 10/12/2010.

The adequacy of the response cannot be determined at this time. Your firm opened CAPA 131 to address the nonconformity by revising the complaint handling procedure (R-QAP-14-2) and MCS Returned Goods Authorization procedure. Per these procedures, complaints are to be created at the receipt of a complaint by any MCS employee. Additionally, your firm has identified a **(b)(4)** as the decided person to facilitate the recording of complaints. However, your firm did not provide a copy of these revised procedures and has not described how the **(b)(4)**interacts with other CMS employees when processing complaints.

4. Failure to establish and maintain adequate procedures to identify the actions needed to correct and prevent recurrence of nonconforming product and other quality problems, as required by 21 CFR 820.100(a)(3). For example: your firm issued seven consecutive requests for Corrective and Preventive Action (CAPA) for subcontractor (request 5-11) to **(b)(4)** pertaining to the **(b)(4)** from 7/08 to 5/09. Specifically, in section 6.4 of Document No. R-QAP-14-1-R04, it is stated that **(b)(4).** Following, in section 6.5, it is stated that **(b)(4)** In request No. 006, Request for Corrective/Preventive Action for Subcontractor, the recommended corrective/preventive action is stated to be **(b)(4)** As such your firm has failed to adequately identify the actions needed to correct and prevent recurrence of nonconforming product and other quality problems.

We reviewed your firm's response and conclude that it is not adequate. Your firm provided memoranda indicating that the seven subcontractor Corrective action requests had been closed out due to the removal of **(b)(4)** from the Approved Vendor List. Additionally, your firm stated that it will conduct a retrospective review of all supplier corrective actions over a period of 12 months to ensure that they were all adequately closed, to be completed by October 2011. However, your firm has not addressed whether a plan will be implemented to address the adequacy of closed CAPAs from other sources or quality data.

5. Failure to establish and maintain adequate 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: **(b)(4).**

The adequacy of the response cannot be determined at this time. Your firm provided records of quality audits based on a full qualit system assessment conducted on May 2011. Additionally, your firm revised the Management Review Procedure, R-QAP-01-1-R06, to require that Management Reviews cannot be finalized without having a report of the results of each quality audit. The next management review will occur in Q3-2011 and in Q1-2012. Your firm did not provide copies of this corrective action.

6. Failure to establish and maintain adequate procedures for identifying valid statistical techniques required for establishing, controlling, and verifying the acceptability of process capability and product characteristics, as required by 21 CFR 820.250(a). For example: **(b)(4)**.

The adequacy of the response cannot be determined at this time. Your firm provided revised copies of its Statistical Techniques Procedure, R-QAP-20-1, to include sample size requirements for quality inspections based on *ANSI Z1.4 Sampling Tables for Inspection by Attributes.* Per this revision, your firm plans to revise its work instructions to identify which AQL will be used for acceptance. Your firm did not provide documentation to demonstrate that these requirements have been implemented in all require Work Instructions, which will ensure that all of your firm's supplied products are inspected per your firm's acceptance activities requirements.

7. Failure to maintain records at the manufacturing establishment or other location that is reasonably accessible to responsible officials of the manufacturer and to employees of FDA designated to perform inspections, as required by 21 CFR 820.180. For example: during the inspection, your firm could not locate complaint #0603, including Medical Device Reporting #9616558-2006-00001, regarding a death of a patient that was treated with the Medical Compression System (MCS) ActiveCare DV System **(b)(6)**. When asked for this file, your firm provided the investigator with a copy of the "MAUDE Adverse Event Report" printed from the FDA's internet website.

The adequacy of the response cannot be determined at this time. Your firm provided revised copies of its Document Control Procedure, R-QAP-05-1, to ensure that all QMS records are organized, contain the appropriate information, and are stored and archived in a known, organized location. As a corrective action, your firm plans to train personnel, conduct an audit of the record retention policy, including an actual review of archived records, and a simulated retrieval exercise. However, your firm did not provide documentation for the proposed corrective action and has not indicated in the Document Control Procedure provided where these documents will be stored.

Our inspection also revealed that your firm's ActiveCare DVT and the ActiveCare + SFT devices are misbranded under section 502(t)(2) of the Act, 21 U.S.C. § 352(t)(2), in that your firm failed or refused to furnish material or information respecting the devic

that is required by or under section 519 of the Act, 21 U.S.C. § 360i, and 21 CFR Part 806 – Medical Devices; Reports of Corrections and Removals. Significant violations include, but are not limited to, the following:

Failure to submit a written report to FDA within 10 working days of initiating such correction or removal, as required by 21CFR 806.10(b). For example: **(b)(4).**

We reviewed your firm's response and conclude that it is not adequate. Your firm conducted a Risk Assessment of the failure mode and submitted an 806 report to the Detroit District Office on 9/25/2011. However, your firm did not define the corrective action, implementation plan, and effectiveness checks to ensure that a correction or removal report is submitted to the agency within the defined timeframe.

Our inspection also revealed that the ActiveCare DVT and the ActiveCare + SFT are adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. § 351(f)(1)(B), because your firm does not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. § 360e(a), or an approved application for an investigational device exemption unde section 520(g) of the Act, 21 U.S.C. § 360j(g). The devices are also misbranded under section 502(o) the Act, 21 U.S.C. § 352(o), because your firm did not notify the agency of its intent to introduce the devices into commercial distribution, as required by section 510(k) of the Act, 21 U.S.C. § 360(k). For a device requiring premarket approval, the notification required by section 510(k) is deemed satisfied when a PMA is pending before the agency. [21 CFR 807.81(b)] The kind of information that your firm needs to submit in order to obtain approval or clearance for the device is described on the Internet at http://www.fda.gov/cdrh/devadvice/3122.html [1]. The FDA will evaluate the information that your firm submits and decide whether the product may be legally marketed

Specifically, the ActiveCare DVT and the ActiveCare + SFT were cleared under K023573 and K060146, respectively. Our inspection revealed that your firm modified the devices by **(b)(4)** to the Active Care DVT and the ActiveCare + SFT **(b)(4)**. A new 510(k) is required for this modification as it represents a significant change to the design of the devices.

Given the serious nature of the violations of the Act, the ActiveCare DVT and ActiveCare + SFT devices manufactured by your firm are subject to refusal of admission under section 801(a) of the Act, 21 U.S.C. § 381(a), in that they appear to be adulterated. As a result, FDA may take steps to refuse these products, known as "detention without physical examination," until these violations are corrected. In order to remove the devices from detention, your firm should provide a written response to this Warning Letter as described below and correct the violations described in this letter. We will notify you if your firm's response appears to be adequate, and we may need to re-inspect your firm's facility to verify that the appropriate corrections and/or corrective actions have been made.

Also, U.S. federal agencies may be advised of the issuance of 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 fifteen business days from the date you receive this letter of the specific steps your firm has taken to correct the noted violations, including an explanation of how your firm plans to prevent these violations, or similar violations, from occurring again. Include documentation of the corrections and/or corrective actions (including any systemic corrective actions) that your firm has taken. If your firm's planned corrections and/or corrective actions will occur over time, please include a timetable for implementation of those activities. If corrections and/or corrective actions cannot be completed within fifteen business days, state the reason for the delay and the time within which these activities will be completed. Please provide a translation of documentation not in English to facilitate our review.

Your firm's response should be sent to: Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Field Operations Branch, White Oak Building 66, RM 2609, 10903 New Hampshire Ave., Silver Spring, MD 20993. Refer to CMS case #222174 when replying**.** If you have any questions about the contents of this letter, please contact: Daniel Walter, Chief, Vascular and Circulatory Support Devices Branch at (301)796-5587 or fax at (301) 847-8138.

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your firm's facility. It is your firm's responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violations noted in this letter and in the Inspectional Observations, FDA 483, issued at the close of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality management systems. Your firm should investigate and determine the causes of the violations, and take prompt actions to correct the violations and bring the products into compliance.

Sincerely yours,
/S/
Steven D. Silverman
Director
Office of Compliance
Center for Devices and
Radiological Health

Links on this page:

1. http://www.fda.gov/cdrh/devadvice/3122.html