



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

July 3, 2008

WARNING LETTER

CHI-3-08

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Sukhwant S. Khanuja
President and CEO
Carematix, Inc.
120 S. Riverside Plaza, Suite 2100
Chicago, IL 60606

Dear Mr. Khanuja:

During an inspection of your firm located in Chicago, Illinois, on March 11 through March 21, 2008, an investigator from the United States Food and Drug Administration (FDA) determined that your firm manufactures the Carematix Wellness System. 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.

Unapproved Device Violations

Our inspection revealed that the Carematix Wellness System is intended for use in measuring peak expiratory flow rate (PEFR) and forced expiratory volume (FEV) using an electronic peak flow meter. Specifically, Hub #103 is intended to be used with the Piko-1 Ferraris Electronic Peak Flow Meter with wireless adapter to measure PEFR and FEV. We also visited your website, located at <http://www.carematix.com>, where you claim that the Carematix Wellness System is intended for use in diagnosing asthma "using a peak expiratory flow meter," diagnosing chronic obstructive pulmonary disease using a spirometer, and monitoring forced expiratory flow in clinical trials.

A review of our records indicates that we cleared your premarket notification [510(k)] for the Carematix Wellness System, K073038, on January 11, 2008. Though you initially sought clearance of this device for indications including spirometry and peak flow measurement, on December 11, 2007, you sent us a letter stating that you "wish to remove all references to spirometry and Peak Flow measurements," since the spirometer used with your predicate device had been discontinued. We did not clear your device for spirometry or peak flow measurement. Thus, promotion of this device for use in conjunction with a

peak flow meter or spirometer for measurement of PEFr and/or FEV is a significant change in intended use that requires submission of a new 510(k). 21 CFR 807.81(a)(3).

Marketing your device for the intended uses listed above that have not been approved or cleared by FDA is a violation of the law. Specifically, the Carematix Wellness System is adulterated under Section 501(f)(1)(B) of the Act, 21 U.S.C. 351(f)(1)(B), because you do 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 (IDE) under Section 520(g) of the Act, 21 U.S.C. 360j(g). The device is also misbranded under Section 502(o) the Act, 21 U.S.C. 352(o), because you did not notify the agency of your intent to introduce the device 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) of the Act, 21 U.S.C. 360(k), is deemed satisfied when a PMA is pending before the agency. 21 CFR 807.81(b). The kind of information you need to submit in order to obtain approval or clearance for your device is described on the internet at <http://www.fda.gov/cdrh/devadvice/3122.html>. The FDA will evaluate the information you submit and decide whether your product may be legally marketed.

FDA requests that you immediately cease marketing the Carematix Wellness System for use in conjunction with a spirometer or peak flow meter to measure PEFr or FEV, or for use in the diagnosis or treatment of any diseases or conditions related to such measurements.

Violations of the Quality System Regulation

This inspection further 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 a response from you dated April 22, 2008, concerning our investigator's observations noted on the Form FDA 483, Inspectional Observations, that was issued to you. 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 procedures for verifying the device design, failure to confirm that the design output meets the design input requirements, and failure to document the results of the design verification, including identification of the design, the methods, the date, and the individuals performing the verification, in the design history file (DHF), as required by 21 CFR 820.30(f).

For example, you failed to have adequate procedures in place for verifying device design activities. Further, the records of design verification activities in the DHF did not include the dates as to when the activities were performed, thereby precluding any effective design review. Design planning and other design control activities have not been effectively corrected and corrective actions have not been instituted even though you have previously identified some of these problems.

We have reviewed your response and have concluded it is inadequate because you have not completed the process of reviewing and updating the DHF, the design control procedures, and the training program. There is also no description in the DHF of the verification or validation activities that will be conducted to assure that the device meets specifications and will perform its intended use(s).

2. Failure to establish and maintain procedures for implementing corrective and preventive action, including requirements for identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems, and requirements for implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems, as required by 21 CFR 820.100(a)(3) and 820.100(a)(5).

For example:

- a. Fifty CAPAs initiated between August 7, 2007, and February 28, 2008, remain open, even though the "Action Plan Due" date has passed for some of these. You have failed to identify or implement the actions needed to correct the quality problems identified in these CAPAs to take systemic corrective action to prevent them from recurring in the future.
- b. CAPA report No. 24 indicates that there are no records of review performed for your suppliers, as required by 21 CFR 820.50. You failed to identify, approve, or implement any action to address this issue.

We have reviewed your response and have concluded it is inadequate for the following reasons:

- You state that you have made some personnel changes, are implementing a plan to review and close open CAPAs, and are conducting internal auditing to verify the effectiveness of your corrective actions. However, you have not yet completed these actions or provided documentation of their completion to FDA for review.

- You state that you plan to audit all supplier records, update the approved vendor's list, and revise the Engineering Change Order procedure, but these have not been completed or submitted to FDA for review.
3. Failure to establish and maintain procedures for implementing corrective and preventive actions, including requirements for investigating the cause of nonconformities related to products, processes, and the quality system, as required by 21 CFR 820.100(a)(2).

For example, the investigator observed two nonconformities with the Carematix Wellness System: (a) after the batteries are first installed in a brand new meter, the meter timer needs to advance one count before the meter will synchronize to the adapter properly; and (b) under certain circumstances, the adapter will send a special record with an incorrect diagnostic reading (all zeros) to the portal. You failed to investigate the cause of these nonconformities, determine whether they are system-wide, or undertake any action to correct them or prevent them from recurring in the future.

We have reviewed your response and have concluded it is inadequate for the following reasons:

- The procedure "Packaging of Devices for Shipment Work Instruction," doc. no. 50.080.00, Rev. 0, to ensure initial meter count advancement by containing specific instructions to install the battery during packaging, has not been completed or submitted for review.
 - Verification test procedure, doc. no. 10.060.00-TP, to verify special record suppression, has not been completed or submitted for review.
 - To prevent recurrence of verification issues, you state that you will implement a problem tracking procedure and reporting mechanism. However, it has not been completed or submitted for review.
4. Failure to review, evaluate, and investigate any complaint involving the possible failure of a device, labeling, or packaging to meet any of its specifications, as required by 21 CFR 820.198(c).

For example, from January 9, 2007 to December 14, 2007, you received twenty-four (24) complaints involving the failure of the Carematix Wellness System to meet its specifications. Though your system indicated that each of these complaints needed investigation, you failed to investigate or close any of them by the time of the inspection in March 2008.

In your response you indicate that you have addressed and closed these 24 complaints, revised your complaint handling procedure, (SOP 852.00-A and form F 852.00-A.), implemented employee training on these revised SOPs, and are revising your complaint procedures and Work Instructions to establish time limits for closure. However, your response is inadequate because you have failed to submit your revised procedures to FDA for review.

5. Failure to establish and maintain procedures to ensure that complaints are evaluated to determine whether the complaint represents an event which is required to be reported to FDA under 21 CFR Part 803, Medical Device Reporting (MDR), as required by 21 CFR 820.198(a)(3).

For example, you failed to evaluate any of the complaints reviewed by the investigator for events which must be reported under the MDR regulation.

We have reviewed your response and acknowledge that you have reviewed the above referenced complaints for MDR reportability, have released a new MDR procedure and are currently providing employee training on it, and are in the process of revising your Complaint SOP. However, your response is inadequate because you have not submitted your revised procedures to FDA for review. Without reviewing your revised MDR and complaint handling procedures, we cannot assess whether your review of the complaints for MDR reporting was adequate or whether your revised procedures are adequate to prevent these violations from recurring in the future.

6. Failure to maintain complaint files and ensure that all complaints are processed in a uniform and timely manner, as required by 21 CFR 820.198(a)(1).

For example, many sections of the complaint forms reviewed during the inspection, such as "Section B: Patient/Provider Involved Information," were not completed, even though your forms indicated these fields should have been filled.

We have reviewed your response and have concluded it is inadequate because you have not amended your complaint handling procedures or otherwise indicated how you plan to prevent this violation from recurring in the future.

7. Failure to establish and maintain procedures for finished device acceptance to ensure that each production run, lot, or batch of finished devices meets acceptance criteria, and is not released into distribution until the activities required in the DMR are completed, the associated data and documentation is reviewed, the release is authorized by the signature of a designated individual, and the authorization is dated, as required by 21 CFR 820.80(d).

For example:

- a. The device history record (DHR) titled "Packing Checklist" for the Carematix Wellness Monitoring System does not have the following items checked off or initialed as completed: "Velcro is placed under front flap," "Record customer number and shipping location at the top of this checklist," and, "Date and initial the bottom of this checklist."
- b. You failed to follow SOP 7.2A-2A, which states in section 6.15, "Match Request for Packaging to Enrollment Form from customer, and verify that all requested devices have been packaged for patient." You failed to complete the verification as required by the procedure. You received at least one complaint from a customer indicating that the customer's device had a different serial number from that identified on the Carematix documentation.
- c. The procedures entitled "Packaging of Rental Devices" and "Enrolling Patients in Device Rental Program" do not designate an individual to review the associated data and documentation and to authorize the release of a finished device for distribution.

We have reviewed your response and acknowledge that you are revising SOP 7.2A-2A, related forms and Work Instructions, revising your packaging and complaint procedures and associated Work Instructions, examining and reviewing your DHR record forms, and implementing a new training procedure. However, your response is inadequate because you have not completed these corrections and you have not submitted your revised procedures to FDA for review.

8. Failure to establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements, failure to evaluate and select potential suppliers, contractors, and consultants on the basis of their ability to meet specified requirements and failure to document the evaluation, as required by 21 CFR 820.50(a)(1).

For example, SOP 741-00-B, "Vendor Qualification," issued on October 1, 2007, requires a vendor qualification record for vendors. Completion of the record includes an evaluation of the supplier's ability to meet Carematix's requirements. You have failed to complete these evaluations for any vendors. There is no vendor qualification record for [REDACTED] (formerly [REDACTED]) located at [REDACTED] which provided the electronic peak flow meter. After the supplier evaluation, the vendor is added to the firm's "Approved Vendors List." The supplier, [REDACTED] is not on the firm's current list.

We have reviewed your response and have concluded it is inadequate because you have not completed the corrections and you have not submitted the revised procedures to FDA for review, including the vendor qualification SOP, the ECR procedure, and the procedure to address the new training. You have also failed to explain how using a Bill of Materials is an adequate basis for vendor qualification auditing.

9. Failure to ensure that all personnel are trained to adequately perform their assigned responsibilities and to document the training, as required by 21 CFR 820.25(b).

For example, your training records contain no documentation of any training between June 2007 and September 2007 on SOPs #7.2A-2A, 7.5A-2, 7.2A-2B, 7.5C-2, or the assembly of devices.

We have reviewed your response and have concluded it is inadequate because you have not completed the training or the revision of the training procedure no. 90.620.00.

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.

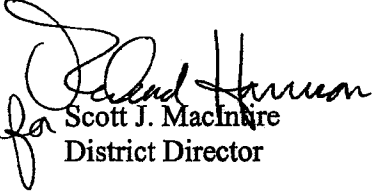
Please notify this office in writing within 15 working days from the date you receive this letter of the specific steps you have taken to correct the noted violations, including an explanation of how you plan to prevent these violations, or similar violations, from occurring again. Include documentation 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.

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 (FDA 483), issued at the closeout of the inspection may be symptomatic of serious problems in your firm's manufacturing

and quality assurance systems. You should investigate and determine the causes of the violations, and take prompt actions to correct the violations and to bring your products into compliance.

Your response should be sent to Lorelei Jarrell, Compliance Officer, Food and Drug Administration, 550 W. Jackson Blvd., 15th Floor, Chicago, IL 60661. If you have any questions about the content of this letter please contact Ms. Jarrell at 312-596-4216.

Sincerely,


for Scott J. MacInire
District Director