DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
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December 5, 2008

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

In reply refer to Warning Letter SEA 09-07

Gerry Cook, President
Pneumex, Incorporated
2605 N Boyer Avenue
Sandpoint, Idaho 83864

WARNING LETTER

Dear Mr. Cook:

During an inspection of your firm located at 2605 N Boyer Avenue, Sandpoint, Idaho, on July 28 through July 29, 2008, an investigator from the United States Food and Drug Administration (FDA) determined that your firm manufactures the following products: Pneu-MAP, Pneu-Back Chair, Pneu-Weight (Single, Double, and Triple), Pneu-Lift, Pneu-Walker (Adult and Pediatric), Pneu-Vibe (Club and Pro), Plinth Vibration table, and Vibro Trac table. 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.

Our inspection revealed that the Pneu-MAP and Pneu-Back Chair are 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). These devices are 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 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) of the Act, 21 U.S.C. 360(k), is deemed satisfied when a PMA is pending before the agency. 21 C.F.R. 807.81(b). The kind of information you need to submit in order to obtain approval or clearance for your devices is described on the Internet at http://www.fda.gov/cdrh/devadvice/3122.html. FDA will evaluate the information you submit and decide whether your products may be legally marketed.

A review of your device labeling entitled *Pneumex *** Try something Pneu... *** :Pneu-Scoliosis™ Program*, revision date September 11, 2007, indicates that Pneu-MAP obtains topographic measurements of the position of vertebrae, utilizes a computer algorithm to compare these positional measurements to those of a "normal" spinal curve, and provides a detailed protocol for treatment and correction utilizing the Pneu-Back Chair. Within the context of the Pneu-Scoliosis™ Program, therefore, the Pneu-MAP device is intended to be used for the diagnostic evaluation of spinal curve abnormalities, and the Pneu-Back Chair is intended to be used as a scoliosis treatment modality.

Although the Pneu-MAP is a commercially distributed class I device (21 CFR 890.1600) and the Pneu-Back Chair is a commercially distributed class II device (21 CFR 890.1925) for which FDA has granted exemptions from the requirement of premarket notification, the devices remain subject to the limitations in 21 CFR 890.9. One such limitation, under 21 CFR 890.9(a), requires a manufacturer to submit a premarket notification to FDA, before introduction or delivery for introduction into interstate commerce, for any exempt device whose intended use is different from the intended use of a legally marketed device in that generic type of device.

The Pneu-MAP has been identified as an intermittent pressure measurement system under 21 CFR 890.1600. This section of the regulations identifies this generic type of device as an evaluative device intended for medical purposes, such as to measure the actual pressure between the body surface and the supporting media. Therefore, the labeling of the Pneu-MAP for the diagnosis of scoliosis is a different intended use from the intended uses of legally marketed devices identified in 21 CFR 890.1600. Similarly, the Pneu-Back Chair has been identified as an isokinetic testing and evaluation system under 21 CFR 890.1925. This section of the regulations identifies this generic type of device as a rehabilitative exercise device intended for medical purposes, such as to measure, evaluate, and increase the strength of muscles and the range of motion of joints. Therefore, the labeling of the Pneu-Back Chair for the treatment of scoliosis is a different intended use from the intended uses of legally marketed devices identified in 21 CFR 890.1925. As a result, pursuant to 21 CFR 890.9, you are required to submit a premarket notification to FDA before introducing or delivering into interstate commerce for commercial distribution the Pneu-MAP and Pneu-Back Chair.

This inspection also revealed that the Pneu-MAP, Pneu-Back Chair, Pneu-Weight (Single, Double, and Triple), Pneu-Lift, Pneu-Walker (Adult and Pediatric), Pneu-Vibe (Club and Pro), Plinth Vibration table, and Vibro Trac table 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.

These violations include, but are not limited to, the following:

1. Failure to establish and maintain plans that describe or reference the design and development activities and define responsibility for implementation, as required by 21 CFR 820.30(b). For example, our investigator found that you have developed design and development plans for the Vibro-Trac table product under Standard Operating Procedure #003, Design and Development Control, but you have not implemented the plans.

2. 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. The design input requirements shall be documented and shall be reviewed and approved by a designated individual(s), as required by 21 CFR 820.30(c). For example, you have not documented or approved any design input requirements for the Vibro-Trac table.

3. Failure to establish and maintain procedures for verifying the device design, as required by 21 CFR 820.30(f). For example, you do not have any documentation in the design history file of any results of design verification for the Vibro-Trac table.

4. Failure to establish and maintain acceptance procedures to ensure that specified requirements for in-process and finished products are met, as required by 21 CFR 820.80(c) and (d). For example, the production records related to in-process and finished device acceptance, required to be completed by production personnel during the assembly of the Pneu-Back Chair sub-assemblies and finished product, have not been maintained since 2004.

5. Failure to establish procedures for quality audits and conduct such audits, as required by 21 CFR 820.22, where "quality audit" is defined under 21 CFR 820.3(t), as a systematic, independent examination of a manufacturer's quality system that is performed at defined intervals and at sufficient frequency. For example, you have not established procedures for quality audits to be performed at defined intervals. Your Standard Operating Procedure #008, Internal Auditing Procedure, states that "Audits will be numbered in chronological order by the calendar year in which performed (e.g. the first audit of 2002 will be numbered 1-02, the second 2-02, etc. The first audit of 2003 will be number 1-03, etc.)." While this SOP guideline suggests that multiple audits will be performed annually, our investigator found you have not performed a quality audit for any of your manufactured devices since 2004.

6. Failure to document the dates and results of quality system reviews by management with executive responsibility, as required by 21 CFR 820.20(c). For example, you told our investigator that you held management review meetings.

However, no dates or results of quality system reviews for any of your manufactured devices were documented.

7. Failure to designate an individual(s) to review for adequacy and approve prior to issuance all documents established to meet the requirements in 21 CFR part 820, and failure to document the date and signature of the individual(s) approving the document, as required by 21 CFR 820.40(a). For example, our investigator noted several documents without approval signatures and dates to confirm approval. The documents include the following:

    a. Pneu-Back Chair assembly procedure, established to meet 21 CFR 820.70.

    b. Standard Operating Procedure #001, Document Control and Change Order System, established to meet 21 CFR 820.40.

    c. Standard Operating Procedure #004, Customer Complaint/Returned Goods Procedure, established to meet 21 CFR 820.100 and 820.198.

    d. Standard Operating Procedure #008, Internal Auditing Procedure, established to meet 21 CFR 820.22.

    e. Standard Operating Procedure #003, Design Development and Control, established to meet 21 CFR 820.30.

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 FDA 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 fifteen (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.

Your response should be sent to the Food and Drug Administration, Attention: Lisa M. Elrand, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington, 98021-4421. If you have any questions about the content of this letter please contact Lisa M. Elrand at (425) 483-4913.

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.

Sincerely yours,

Charles M. Breen
District Director