Inspections, Compliance, Enforcement, and Criminal Investigations

Phoenix Medical Devices, LLC 9/29/2009

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Los Angeles District
19701 Fairchild
Irvine, California 92612-2506
Telephone (949) 608-2900
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WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

W/L 31-09

September 29, 2009

James H. Klett, President
Phoenix Medical Devices, LLC
2458 Alton Parkway
Irvine, CA 92606-5037

Dear Mr. Klett:

During an inspection of your firm, located in Irvine, California from March 19 to May 13, 2009, investigators from the United States Food and Drug Administration (FDA) determined that your firm manufactures the *Duet, Duet+, Duet Pain*

Solutions Kit, Quartet, Duet Therapy Garment Kit, and SOLO Therapy Supply Kit. 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 *Duet+, Duet Pain Solutions Kit, Quartet, Duet Therapy Garment Kit, and SOLO Therapy Supply Kit* as well as the private label versions of these devices **(b)(4)** are adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. § 351(f)(1)(B), because you do not have approved application for pre-market approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. § 360e(a), or approved applications 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) of the Act, 21 U.S.C. § 252(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) in that a notice or other information respecting the modification to the device was not provided to the FDA as required by section 510(k), 21 U.S.C. § 360(k), and 21 CPR § 807.81(a)(3)(i). 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.

Specifically, the PMD-2000, now branded as the *Duet*, was cleared via K042881 for muscle and nerve stimulation using two therapy modes: (1) interferential current stimulation for symptomatic relief of acute pain, symptomatic management and relief of chronic pain, and for adjunctive treatment for the management of post traumatic and post-surgical pain as well as neuro-muscular stimulation to treat various conditions; and (2) neuromuscular stimulation for relaxation of muscle spasms, prevention or retardation of disuse atrophy, increasing local blood circulation, muscle re-education, immediate post surgical stimulation of calf muscles to prevent venous thrombosis, and maintaining or increasing range of motion. The *Duet+* and *Quartet* devices contain the following changes or modifications in the Duet that can significantly affect the safety and effectiveness of the device and requires a new 510(k) submission: (1) the *Duet's* peak output voltage of 22.5 Volts (45 Volts peak-to-peak) has been increased to 25 Volts (50 Volts peak-to-peak) through the **(b)(4)** (2) optional rechargeable **(b)(4)** batteries; and (3) eight additional preset therapy protocols not available in the *Duet*. These eight additional protocols consist of two muscle stimulation modes ("Russian" stimulation with 1000 Hz and 2500 Hz carrier frequencies), three sequential stimulation modes of muscle stimulation followed by interferential stimulation, and three (reversed) sequential stimulation modes of interferential stimulation followed by muscle stimulation.

In addition, no electrodes were included with the clearance of the PMD-2000, *Duet*, via K042881. The Instruction Manual stated that "[t]he PMD-2000 is not supplied with electrodes. Phoenix Medical Devices recommends the **(b)(4)** The *Duet Pain Solutions Kit, Duet Therapy Garment Kit,*and *SOLO Therapy Supply Kit* contain SOLO Therapy Electrodes, also described as "gel foam electrodes." These electrodes represent a major change or modification in the *Duet* that can significantly affect the safety and effectiveness of the device and requires a new 510(k) submission. If the SOLO Therapy Electrodes have FDA clearance, please provide us with the 510(k) clearance number.

Our inspection also 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 manufacturing, packaging, storage, or installation are not in conformance with the Good Manufacturing Practice (GMP) requirements for the Quality System Regulation, specified in 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 a design history file that contains or references the records necessary to demonstrate that the design was developed in accordance with the approved design plan and the design control requirements, as required by 21 CFR § 820.30(j). For example:

a. There is no design history file for the *Duet*+ stimulator;

b. There is no specific design plan for the *Duet*+ or *Quartet* model stimulators;

c. There is no approved design input for the 2 channel *Duet*+ stimulator designed with 23 protocols or for the 4 channel *Quartet* stimulator designed with 23 protocols. Protocols are preset/preprogrammed output therapy parameters that include the interferential frequency level as well as the type of muscle stimulation;

d. There is no raw data to support design verification for the *Duet* and *Quartet;*

e. Design validation for *Duet, Duet*+, and *Quartet* did not include testing under actual or simulated conditions, i.e., assessment of human factors;

f. Specifications for the electrodes used in conjunction with the *Duet* device are not included as design inputs; and

g. The Design Review Minutes, Doc No: 07-05-004, lacked signature, date and attendees.

2. Failure to establish and maintain procedures for acceptance of incoming product that ensures incoming product is inspected, tested, or otherwise vel1fied as conforming to specified requirements; and acceptance or rejection shall be documented as required by 21 CFR § 820.80(b). For example:

a. There are no procedures or specifications for the acceptance of incoming gel foam electrodes that are supplied inside the *SOLO Therapy Supply Kit*, and fabric electrodes supplied in the *Duet Therapy Garment Kit*;

b. Incoming lead wires are **(b)(4)** according to your procedure Product Verification Lead Wires-Work Instruction, Doc: 05-88-013, Rev A1. According to instruction 3.4, a summary of results are documented in the acceptance records for lead wire testing but individual test results, which would provide an accurate snapshot of actual testing, are not required; and

c. Acceptance cl1teria for pass-fail of incoming battery chargers has not been defined in procedure, Incoming Product Verification Work Instruction-Battery Chargers Doc No.: 05-88-011 Rev C-1.

3. 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, as required by 21 CFR § 820.80(d). For example, you have no established procedures that include finished device acceptance specifications for release of the *SOLO Therapy Supply Kits* and *Duet Garment Kits.*

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

For example, Complaint case #138, opened on 2/12/08 remains open and Case #149, opened 4/9/08 was not closed until 1/13/09. In the instance of Case #138, there is no documentation of complaint follow-up or progress after 2/12/2008.

There is no explanation for the delayed closure of case # 149. Explanation is not provided for the lack of timeliness in complaint closure.

5. Failure to establish and maintain adequate procedures for receiving, reviewing, and evaluating complaints by a formally designated unit, as required by 21 CFR § 820.198 and failure to establish and maintain procedures that 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, as required by 21 CFR § 820.198(a)(3).

For example, your procedure, Customer Satisfaction, Feedback and Complaints, Doc No 05-06-00 Rev E-1, date implemented 1/1/09, does not require an evaluation of complaints for medical device reportable events.

6. Failure to establish and maintain adequate procedures to ensure the investigation of complaints involving the possible failure of a device to meet its specifications, as required by 21 CFR § 820.198 (c). For example,

a. A complaint involving lead wires (case # 185 dated 7/30/08) where a patient's husband requested a replacement set was closed with no evaluation or investigation; and

b. A complaint of a battery exploding (case # 127 dated 12/13/07) in the battery charger was closed on 3/18/08 with no evaluation or investigation.

7. Failure to establish and maintain adequate procedures that ensure when investigations are made that the investigation record includes the nature of the complaint, as required by 21 CFR § 820.198(e)(5). For example:

The nature and details of complaints are not documented in the complaint files as follows:

a. Complaints written on post-it notes attached to 8 stimulators returned to you on 4/24/07 were not documented in the complaint file for case #43 as is required in your procedure Doc: 05-06-000, Customer Satisfaction, Feedback, and Complaints, B-1; and

b. Case# 192 was also generated as a result of stimulator malfunctions, in that

the problem states, "No stim felt or erratic". The complaint investigation describes a software problem which was addressed by loading an updated software version to the Duet device. The root cause of the software problem was not identified and documented in the complaint file.

8. Failure to establish and maintain adequate procedures to ensure the verification or validation of the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device, as required by 21 CFR § 820.100(a)(4).

For example, your procedure Corrective and Preventive Action, Doc No.: 05-09-000 Rev A1, date implemented 1/1/09, makes no reference to verify or validate the corrective actions taken are effective and do not adversely affect the finished device.

9. Failure to validate software used as part of production and quality system for its intended use according to an established protocol, and failure to document the results of the software validation, as required by 21 CFR § 820.70(i).

For example, the **(b)(4)** and **(b)(4)** software used to generate instruction manuals, clinician's manuals and prescription device labels for the *Duet, Duet+, Quartet devices* has not been validated.

10. Failure to establish and maintain adequate procedure to ensure the evaluation of suppliers, contractors, and consultants, as required by 21 CFR § 820.50(a)(1). For example, the independent contractor conducting internal audits **(b)(4)** has no documented training in the FDA Quality System Regulation.

11. Failure to establish and maintain procedures that ensure records of acceptable suppliers, contractors, and consultants are maintained, as required by 21 CFR § 820.50(a)(3). For example, the contractor of internal audits **(b)(4)** lead wire supplier **(b)(4)** software consultant **(b)(4)** and electrodes supplier not listed in your approved supplier list dated Doc 05-19-000 Rev J.

12. Failure to .maintain Device Master Records (DMRs) that include, or refer to the location of, all specifications, as required by 21 CFR § 820.181. For example, you have no device master record for the Duet Therapy Ga17nent Kits and SOLO Therapy Supply Kits.

13. Failure to establish and maintain procedures to control labeling activities, as required by 21 CFR § 820.120.

For example, you have no procedure for generating instruction manuals and clinician's manuals which are included with all finished devices such as the *Duet, Duet+, Quartet* and private labeled devices.

14. Failure to establish and maintain adequate procedures to ensure that equipment calibration dates, individual(s) performing each calibration, and the next calibration date are recorded in the calibration records, as required in 21 CFR § 820.72(b)(2). For example, there is no calibration record for timers used in production and used during design verification of the *Duet* and *Quartet* model stimulators.

Our inspection also revealed that your Duet, Duet Pain Solutions Kit, Duet+, Quartet, SOLO Therapy Supply Kit, Duet Therapy Garment Kit as well as the private labeled versions of these devices **(b)(4)** are misbranded under section 502(t)(2) of the Act, 21 U.S.C. 352 (t)(2), in that you failed or refused to furnish material or information respecting the device that is required by or under section 519 of the Act, 21 U.S.C. 360i, 21 CFR § 803 - Medical Device Reporting (MDR) regulation. Significant deviations include, but are not limited to, the following:

15. Failure to develop and implement an adequate written MDR procedure, as required by 21 CFR § 803.17. For example, Doc No.: 01-000-01, FDA Medical Device Reporting, Revision A1, date implemented 12/1/08, does not provide for the following requirements:

a. MDR forms and instructions for completing the FDA-3500A;

b. An internal system for consistent evaluation of adverse events including a standardized review process to determine when an event meets the criteria to report;

c. A 5-day reporting requirement for reportable events that necessitate remedial action to prevent an unreasonable risk of substantial harm to the public as required in CFR § 803.53; and

d. The address for reporting adverse events.

In addition, the instruction manuals for the *Duet, Duet+, Quartet* indicate "approved for sale by FDA" and the FDA logo is printed on your labeling (webpage) as well as the door leading into the film. This represents misbranding by reference to premarket notification in that any representation that creates an impression of official approval of a device because of complying with the premarket notification regulations is misleading and constitutes misbranding. 21 CFR § 807.97, Please modify all labeling and product to remove references to FDA clearance or approval.

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 ill devices to which the Quality System regulation deviations are reasonably related will not be approved until !be 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.

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 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.

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:

James P. Stumpff
Acting Director, Compliance Branch
Food and Drug Administration
19701 Fairchild
Irvine, CA 92612-2506

If you have any questions about the content of this letter please contact Marco S. Esteves, Compliance Officer at 949-608-4439.

Sincerely,
/S/

Alonza E. Cruse
District Director
Los Angeles District