Inspections, Compliance, Enforcement, and Criminal Investigations

Aionex Inc 1/9/13

Department of Health and Human Services

Public Health Service
Food and Drug Administration
New Orleans District
404 BNA Drive
Building 200- Suite 500
Nashville, TN 37217
Telephone: (615) 366-7801
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AMENDED
(This letter replaces Warning Letter No. 2012-NOL-06 dated January 7, 2013)

January 9, 2013

WARNING LETTER NO. 2013-NOL-06

UNITED PARCEL SERVICE
DELIVERY SIGNATURE REQUESTED

Curt A. Freemeyer, President and CEO
Aionex Inc.
104 Space Park North
Goodlettsville, Tennessee 37072

Dear Mr. Freemeyer:

On November 13, 15-16, and 20, 2012, a United States Food and Drug Administration (FDA) investigator inspected your firm, located at 104 Space Park North, Goodlettsville, Tennessee. The inspection determined your firm is operating as a specification developer of a Class II medical device called *Nurse Call* and as a manufacturer of a software system called *Focus*. When this software is used in conjunction with *Nurse Call*, it is considered a Class I medical device. Under Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 United States Code (USC) 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 these devices are adulterated within the meaning of Section 501(h) of the Act [21 USC 351(h)], because 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. No response has been received from your firm concerning our investigator's observations noted on the FORM FDA 483 (FDA 483), Inspectional Observations, issued to you on November 20, 2012. These violations include, but are not limited to, the

following:

1. Failure to develop, maintain, and implement Medical Device Reporting (MDR) procedures as a manufacturer of a medical device, as required by 21 CFR 803.17. For example, your firm has no formal internal system to evaluate adverse events and submit the required MDR reports to FDA. As a manufacturer of a medical device, your firm is required to establish and maintain written MDR procedures for the following:

a. Internal systems that provide for: 1) Timely and effective identification, communication, and evaluation of events that may be subject to MDR requirements; 2) A standardized review process or procedure for determining when an event meets the criteria for reporting; and 3) Timely transmission of complete medical device reports to manufacturers or to FDA, or to both if required.

b. Documentation and record keeping requirements for: 1) Information that was evaluated to determine if an event was reportable; 2) All medical device reports and information submitted to manufacturers and/or FDA; 3) Any information evaluated for the purpose of preparing the submission of annual reports; and, 4) Systems which ensure access to information that facilitates timely follow up and inspection by FDA.

2. Failure to establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit, as required by 21 CFR 820.198(a). Such procedures shall ensure complaints are evaluated to determine whether the complaint represents an event which is required to be reported to FDA, per 21 CFR 803-MDR, as required by 21 CFR 820.198(a)(3). Specifically, your firm has no standard operating procedures implemented to determine if the complaint received represents an MDR reportable event. Your firm documents complaints in a computer system called "**(b)(4)**"; however, this practice is inadequate because you failed to implement a standard operating procedure to ensure:

a. All complaints are processed in a uniform and timely manner;

b. Oral complaints are documented upon receipt;

c. Complaints are evaluated to determine whether the complaint represents an event which is required to be reported to FDA, as required by 21 CFR 803-MDR.

3. Failure to establish procedures for quality audits and conduct such audits to assure 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. Specifically, you do not have procedures addressing quality audits, nor do you have records documenting quality audits of your facility and suppliers.

4. Failure to implement procedures to ensure all purchased or otherwise received product and services conform to specified requirements, as required by 21 CFR 820.50. Specifically, your firm failed to define, document, and implement purchasing control procedures to ensure the *Nurse Call* hardware purchased from your contract manufacturer conforms to your firm's specified requirements.

5. Failure to establish procedures for corrective and preventive action (CAPA), as required by 21 CFR 820.100(a). For example, your firm failed to establish procedures for the following requirements:

a. Analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems;

b. Investigating the cause of nonconformities relating to product, processes, and the quality

system;

c. Identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems;

d. Verifying or validating the CAPA to ensure such action is effective and does not adversely affect the finished device;

e. Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems;

f. Ensuring information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of such problems; and,

g. Submitting relevant information on identified quality problems, as well as CAPAs, for management review.

6. Failure to establish and maintain adequate procedures to control the design of the device in order to ensure specified design requirements are met, as required by 21 CFR 820.30(a)(1). For example, your firm failed to establish and maintain written procedures to control the design process, including requirements for design inputs, design outputs, design reviews, design verification/validation, design transfer and design changes for the *Nurse Call* and *Focus* devices.

7. Failure to establish and maintain a Design History File (DHF) for each type of device to demonstrate the design was developed in accordance with the approved design plan and design control requirements, as required by 21 CFR 820.30(j). For example, your firm failed to establish a DHF for the *Nurse Call* and *Focus* devices to demonstrate the devices were developed in accordance with an approved design plan and design control requirements, pursuant to 21 CFR 820.30(j).

8. Failure to maintain Device Master Records (DMRs) for your *Nurse Call* device and *Focus* software, as required by 21 CFR 820.181. For example, your firm has not documented, or referenced the location of, the following required information for the devices you manufacture:

a. Device specifications;

b. Production process specifications;

c. Quality assurance procedures and specifications; and,

d. Packaging and labeling specifications.

9. Failure to establish and maintain adequate procedures to ensure Device History Records (DHRs) for each batch, lot, or unit are maintained to demonstrate the device is manufactured in accordance with the DMR, as required by 21 CFR 820.184. For example, your firm failed to establish written procedures for maintaining DHR's. In addition, your firm does not maintain a complete device history which includes all acceptance/release activities and the primary identification label for your *Nurse Call* or *Focus* devices.

10. Failure of management with executive responsibility to review the suitability of the quality system at defined intervals and with sufficient frequency according to established procedures to ensure the quality system satisfies the requirements of this part, as required by 21 CFR 820.20 (c). For example, your firm failed to establish management review procedures and conduct management reviews as a manufacturer of a medical device.

11. Failure to establish procedures for ensuring all personnel are trained to adequately perform their assigned responsibilities and for identifying training needs were not established, maintained, and documented, as required by 21 CFR 820.25(b). For example, your firm failed to document training activities for Aionex Inc. employees involved in manufacturing, complaint and MDR handling, and quality assurance. In addition, procedures for identifying training needs were not established, documented, and implemented to ensure all personnel are trained to perform their assigned duties.

12. Failure of management with executive responsibility to establish policy and objectives for, and commitment to, quality, as required by 21 CFR 820.20(a). Management with executive responsibility shall ensure the quality policy is understood, implemented, and maintained at all levels of the organization. For example, your firm failed to establish policy and objectives for, and commitment to, quality as a manufacturer of medical devices.

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 they may take this information into account when considering the award of contracts. Additionally, premarket approval applications for Class III devices 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.

Additionally, your establishment lacks registration and device listing. Consequently, devices manufactured or distributed by your firm are misbranded under Section 502(o) of the Act [21 USC 352(o)], as they were manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under Section 510 of the Act [21 USC 360]; and not included in a list, as required by Section 510(j) of the Act [21 USC 360(j)].

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 correction 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 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 FDA 483, issued at the close out 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: Ms. Kimberly Dutzek, Compliance Officer, at the address above. If you have any questions about the content of this letter please contact Ms. Dutzek at (615) 366-7826.

Sincerely,
/S/
Patricia Schafer
District Director
New Orleans District

Close Out Letter

- Aionex Inc. - Close Out Letter 8/1/14[1]

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Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

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