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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

APR 2 4 2007

WARNING LETTER

VIA FEDERAL EXPRESS

Mr. Gary McBrown
Quality Manager
G&B Electronic Designs Limited
54, Woolmer Industrial Estate
Bordon, Hampshire, GU35 9QF
United Kingdom

Dear Mr. McBrown:

During an inspection of your firm located in Bordon, Hampshire, from November 20-23, 2006, an investigator from the United States Food and Drug Administration (FDA) determined that your firm manufactures the TrackIt and NicoletOne Ambulatory Electroencephalograph Recorder devices. 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)), 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 (C.F.R.), Part 820. These violations include, but are not limited to, the following:

1. Failure to assure that when the results of a process cannot be fully verified by subsequent inspection and test, the process shall be validated with a high degree of assurance and approved according to established procedures, as required by 21 CFR 830.75(a). For example:

    a. Automated machines were used for the screening, placing, and soldering processes for the circuit boards used in the NicoletOne device but no procedures were established to validate the processes to assure that specified requirements are met.

b. There are no written procedures for ensuring the installation, operation, or performance of the NicoletOne device for the automated screen printing machine, automated pick and place machine, and the reflow oven.

We have reviewed your response and have concluded that it is inadequate because you have confused process validation with equipment qualification. Also, no procedures have been submitted for review and no timetable for corrective action and response was indicated.

2. Failure to assure that when computers or automated data processing systems are used as part of the production or quality system the manufacturer shall validate computer software for its intended use according to an established protocol, as required by 21 CFR 820.70(i). For example, electronic records are used, but there was no software validation. No procedures are established to validate for its intended purpose the Microsoft Word or Microsoft Excel software used in creating and maintaining nonconformance records, product return records, internal audit corrective action records, or preventive action records.

   We have reviewed your response and have concluded that it is inadequate because off-the-shelf software must be validated for its intended purpose. You have stated that a review will be conducted of the existing forms and an implementation of a new record control system to meet FDA requirements will be pursued. A new system may not be necessary; however, no procedures have been submitted for review and no timetable for corrective action and response was indicated.

3. Failure to establish and maintain adequate procedures to control product that does not conform to specified requirements. The evaluation of nonconforming product shall include a determination of the need for an investigation and notification of the persons responsible for the nonconformance. The evaluation of nonconforming product and any associated investigation shall be documented, as required by 21 CFR 90(a). For example, nonconformance report no. 1073 describes the need to relabel a device by a customer. The record does not include any analysis or other documentation of an evaluation into this nonconformance.

   We have reviewed your response and have concluded that it is inadequate because it does not address the FDA 483 citation and it appears that you are unaware there is no requirement to report to FDA all nonconformances. FDA must be notified only under the requirements of the Medical Device Reporting regulation, the Corrections and Removals regulation, and the Recall regulation.

Our inspection also revealed that your TrackIt and NicoletOne Ambulatory EEG 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 device that is required by or under section 519 of the Act, 21 U.S.C. 360i and 21 C.F.R. Part 806 – Reports of Corrections and Removals regulation. Significant deviations include, but are not limited to, the following:

4. Failure to submit a written report to FDA of any correction or removal of a device, as required by 21 CFR 806.10. For example, nonconformance report no. 1073 describes the need to relabel a device by a customer. The record does not include a heath hazard analysis or other documentation of an evaluation to justify why a field correction was not reported to the FDA.

   We have reviewed your response and have concluded that it is inadequate because you did not provide justification for not reporting the correction or removal action to FDA which shall contain conclusions and any follow-ups, and be reviewed and evaluated by a designated person.

Our inspection also revealed that your TrackIt and NicoletOne Ambulatory EEG devices are misbranded under section 502(o) of the Act, 21 U.S.C. 352(o), in that your firm failed or refused to furnish material or information respecting the device that is required by or under section 510 of the Act, 21 U.S.C. 360(i)(1) and 21 C.F.R. Part 807 – Establishment Registration and Device Listing for Manufacturers and Initial Importers of Devices regulation. Significant deviations include, but are not limited to, the following:

5. Failure to assure that any establishment within any foreign country engaged in the manufacture, preparation, propagation, compounding, or processing of a device that is imported or offered for import into the United States shall register and list such devices in conformance of such requirements of Subparts B. The official correspondent for the foreign establishment shall facilitate communication between the foreign establishment's management and representatives of the Food and Drug Administration, as required by 21 CFR 807.40(a). For example, the inspection revealed your firm has not registered or listed with the FDA and you are importing devices into the United States.

   We have reviewed your response and have concluded that it is inadequate because you have not registered or listed your devices with the FDA, and have not identified your US agent.

A followup inspection will be required to assure that corrections are adequate. We will contact the appropriate people and request an establishment re-inspection. An FDA trip planner will be in touch with you to arrange a mutually convenient date for this inspection.

You should take prompt action to correct the violations addressed in this letter. Failure to promptly correct these violations may result in regulatory action, which may include detaining your devices without physical examination upon entry into the United States until the corrections are completed, Section 801(a) of the Act (21 U.S.C. § 381(a)). Also, U.S. 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: Nicole L. Wolanski, Chief, Cardiovascular and Neurological Devices Branch, Division of Enforcement B, Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850. If you have any questions about the content of this letter please contact her via telephone at 240-276-0295, or via fax at 240-276-0129.

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,

Timothy A. Ulatowski
Director
Office of Compliance
Center for Devices and
Radiological Health