U.S. Department of Health & Human Services

U.S. Food and Drug Administration

Inspections, Compliance, Enforcement, and Criminal Investigations

Cranial Solutions 6/21/10

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Central Region
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

Telephone (973) 331-4906

June 21, 2010

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Kirk A. Lucyk
Cranial Solutions
602 Lincoln Avenue
Pompton Lakes, NJ 07442

10-NWJ-12

Dear Mr. Lucyk:

During an inspection of your firm located in Pompton Lakes, New Jersey, on May 5, 2010 through May 14, 2010, investigators from the United States Food and Drug Administration (FDA) determined that your firm is a manufacturer o Cranial Orthosis. Under section 201(h) of the Federal Food, Drug, and Cosmetic Act ("the Act") [21 U.S.C. § 321(h)] this product is a device because it is intended for use in the diagnosis of disease or other conditions or in the cure, mitigation treatment, or prevention of disease, or is intended to affect the structure or function of the body.

At the close of the inspection, FDA Investigators discussed with you objectionable conditions observed during the inspection. A Form FDA-483 was issued to you. The FDA inspection revealed that your device is 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 procedures for implementing corrective and preventive action (CAPA) as required by 21 CFR § 820.100(a).

Specifically, your firm's Corrective and Preventive Action procedure (procedure includes no signature and date of approval for implementation and no revision history) does not include requirements for analyzing concessions, quality audit reports, quality records, service records, all complaints received by your firm, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems. For example, your written Corrective and Preventive Action procedure fails to require identifying and documenting data sources and their data elements, both internal and external to your firm, in order to perform measurements an

statistical techniques for the analysis of nonconformity or a potential nonconformity that may require an investigatior (identifying the root cause). Furthermore, your procedure fails to provide for control and action to be taken on devices distributed, and those not yet distributed, that are suspected of having potential nonconformities.

2. Failure to establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before there implementation as required by 21 CFR § 820.30(i).

Specifically, your firm's design change request form and design change review form included with your CSO Design Change procedure (procedure includes no signature and date of approval for implementation and no revision history) does not require validation or verification of design changes before there implementation. Your firm has failed to ensure that after the design requirements are established and approved, changes to the design, both pre-production and post-production are also validated (or verified where appropriate), and approved before implementation.

3. Failure to establish and maintain procedures for acceptance of incoming product as required by 21 CFR § 820.80(b). Specifically, your firm has failed to establish a written procedure for incoming product to be inspected, tested, or otherwise verified as conforming to specified requirements. This was a repeat violation from a previous inspection.

4. Failure to maintain device master records (DMR's) as required by 21 CFR § 820.181. Specifically, your firm has no established and maintained DMRs, that include, or refer to the location of the device specifications, production process specifications, quality assurance procedures and specifications, packaging and labeling specifications, and installation, maintenance, and servicing procedures and methods, for its Cranial Orthosis devices.

5. Failure to establish a quality plan which defines the quality practices, resources, and activities relevant to devices that are designed and manufactured as required by 21 CFR § 820.20(d). This was a repeat violation from a previous inspection.

6. Failure to establish and maintain procedures to control all documents that are required by 21 CFR § 820.40 (a). Specifically, your firm does not document the approval date nor the signature of the approving official for your CSO Equipment Calibration Procedure, Document Controls Procedure, Corrective and Preventive Action Procedure, CSO Design Change Procedure, Cranial Solutions Quality Audit Procedure, and Medical Device Reporting Procedure. Furthermore, any changes to these documents have not been recorded as required by 21 CFR § 820.40 (b).

Furthermore, our inspection revealed that you have not registered your facility as a medical device manufacturer. Failure to register a facility with FDA constitutes misbranding under section 502(0) of the Act, 21 U.S.C. § 352(0), in that your devices were manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under Section 510, 21 U.S.C. § 360. You can obtain the registration form from our website at http://www.fda.gov.

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 FDA without further notice. These actions include, but are no 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 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: Robert J. Maffei, Compliance Officer, U.S. Food and Drug Administration, 10 Waterview Boulevard, 3rd Floor, Parsippany, New Jersey, 07054. If you have any questions about the content of this letter, please contact Mr. Maffei at 973-331-4906.

Finally, you should know that this letter is not intended to be an all-inclusive list of the violation(s) 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 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,
/S/

Diana Amador-Toro
District Director
New Jersey District Office

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