U.S. Food and Drug Administration

Inspections, Compliance, Enforcement, and Criminal Investigations

Compass International Innovations Inc. 5/23/11

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Minneapolis District Office
Central Region
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May 23, 2011

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 11 – 31

Jon S. Rousu
President
Compass International Innovations Inc.
1815 14th Street NW
Rochester, Minnesota 55901

Dear Mr. Rousu:

During an inspection of your firm located in Rochester, Minnesota on March 3-7, 2011, an investigator from the Food and Drug Administration (FDA) determined that your firm manufactures stereotactic position systems and CT stereotactic adaptation systems. 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 (21 CFR), Part 820. We received a response from you dated March 9 2011, concerning our investigator's observations noted on the Form FDA 483, List of Inspectional Observations, that was issued to you; we address this response below. Your violations include, but are not limited to, the following:

1. Failure to establish and maintain procedures for validating the device design, i.e. software validation, which is required by 21 CFR 820.30(g). For example, your firm did not establish a software validation procedure or a software validation plan for software version 12.1.

   We acknowledge, since the release of software version 12.1 on August 27, 2008, that you have conducted a retrospective software validation for software versions 10.14-12.1; however, this was not conducted until June 8-August 20, 2010. Additionally, our inspection noted these "retrospective" testing activities lacked testing activities typically performed during a software validation, such as updated software requirements specification, a source code evaluation, and user site testing.

2. Failure to establish and maintain complaint files as required by 21 CFR 820.198. For example, your procedure CII-RA-003 Product Complaint System and you form CII-RA-F-100 Product Complaint Form have not been implemented. Customer communications involving complaints were not identified as complaints and were, therefore, not processed as such. The result was no evaluation to determine whether the complaint represented a reportable event; a complaint investigation was not conducted and the rationale was not documented.

3. Failure to evaluate and select potential suppliers on the basis of their ability to meet specified requirements including quality requirements and documentatio of such evaluation as required by 21 CFR 820.50(a)(2). For example, no supplier evaluation or qualification activities have been performed or documented.

4. Failure to establish and maintain adequate procedures to control product that does not conform to specified requirements, as required by 21 CFR 820.90(a). For example, your procedure CII-QS-007 Control of Non-Conforming Items had not been fully implemented; the evaluation, segregation, and disposition of nonconforming product is not documented.

5. Failure to conduct quality audits to assure that 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. For example, your procedure CII-QS-010 Internal Audit Procedure has not been implemented; no internal quality audits have been performed.

Your response dated March 9, 2011, to the Form 483 did not provide enough information for us to fully assess your corrective actions. Documentation of corrections (e.g., revised procedures and forms and evidence of implementation) was not provided. A follow-up inspection will be necessary to assess whether your corrective actions are complete and fully implemented.

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 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 Demetri L. Lueneburg, Compliance Officer. If you have any questions about the content of this letter, please contact Ms. Lueneburg at (612) 758-7210.

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, 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.

Sincerely,

/s/

Gerald J. Berg
Director
Minneapolis District

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