Inspections, Compliance, Enforcement, and Criminal Investigations

UltraRad Corporation 5/29/09

Department of Health and Human Services

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

Telephone (973) 331-4906

May 29, 2009

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

David J. Mahoney
President -
UltraRad Corporation
301 Pinedge Drive
West Berlin, NJ 08091

09-NWJ-04

Dear Mr. Mahoney:

During the inspection of your firm, UltraRad Corporation, located at 301 Pinedge Drive, West Berlin, New Jersey on February 23, 2009 through March 5, 2009, our investigator from the United States Food and Drug Administration (FDA) determined that your firm manufactures UltraPACS. 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.

This inspection revealed that this 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, its 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. No written response was received from you concerning our investigator's observations noted on the Form FDA 483, List of Inspectional Observations that was issued to William J. Giunta, Vice President of Service, on March 5, 2009. These violations include, but are not limited to, the following:

1. Failure to establish and maintain procedures for implementing corrective and preventative action that includes 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 as required by 21 CFR § 820.100(a)(1). Specifically, your firm has failed to establish and implement a Corrective and Preventive Actions (CAPA) procedure that requires identifying quality data sources to be analyzed for the need for corrective and preventative actions. Although your film's CAPA & Customer Complaints Procedure, 200-104, describes the process used to analyze and investigate. customer complaints for the need for corrective and preventive action, there was no procedure that requires examining other sources of quality data to identify and develop the extent of product and quality problems. This was a repeat violation from a previous FDA-483 that was issued to your firm.

2. Failure to establish and maintain procedures for receiving, reviewing, and evaluating complaints to determine whether the complaint represents an event which is required to be reported to FDA under part 803, Medical Device Reporting, as required by 21 CFR § 820.198(a)(3). Specifically, your firm has failed to establish and maintain procedures for evaluating complaints received to determine whether or not the complaint should be filed as a Medical Device Report. Your firm's CAPA & Customer Complaints Procedure, 200-104, does not require any evaluation to determine if the complaint (adverse event) should be reported as a Medical Device Report. For example, your HEAT software that is

used to track and record customer complaints has no reference fields to identify any complaints that would meet the requirements for Medical Device reporting under 21 CFR part 803. This was a repeat violation from a previous FDA-483 that was issued to your firm.

3. Failure to establish procedures for quality audits and conduct such 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. Specifically, your firm has failed to implement Quality Management procedure 200-111 since no annual company wide quality audit was performed for 2008. You failed to audit all facets of the quality program as described in your written procedure. Furthermore, your quarterly audit report forms fail to include all areas of the quality system. For example, your quality audit report question sheet does not include document control (appropriate procedure versions available, document change procedure followed if procedures changed), management reviews (management reviews documented. dated, attended, and scheduled per procedural requirements), and training (employees trained on new/changed procedures). This was a repeat violation from a previous FDA-483 that was issued to your firm.

4. Failure to validate computer software for its intended use according to an established protocol when computers or automated data processing systems are used as part of production or the quality system as required by 21 CFR § 820.70 (i). This was a repeat violation from a previous FDA-483 that was issued to your firm. For example:

A) Your firm uses off-the-shelf software (HEAT Help Desk) to manage customer support service calls and to maintain customer site configuration information; however, your firm failed to adequately validate this software in order to ensure that it will perform as intended in its chosen application. Specifically. your firm's validation did not ensure that the details screen was functioning properly as intended. The details screen is used to capture complaint details and complaint follow-up information which would include corrective and preventative actions performed by your firm when service calls are determined to be CAPA issues.

B) Off-the-shelf software (Microsoft SharePoint) is being used by your firm to manage your quality system documents for document control and approval. However, your firm has failed to adequately validate this software to ensure that it meets your needs and intended uses. Specifically. at the time of this inspection there were two different versions of your CAPA & Customer Complaint procedure, SOP-200-104; however, no revision history was provided on the SharePoint document history. Your firm has failed to validate the SharePoint software to meet your needs for maintaining document control and versioning.

5. Failure to establish procedures for identifying training needs and ensure that all personnel are trained to adequately perform their assigned responsibilities as required by 21 CFR § 820.25(b). Specifically, your firm has no written procedure identifying how and when employee training was to be performed, and the identification of training needs. Your firm has failed to ensure that personnel are trained to adequately perform their assigned duties and how their particular job relates to the overall quality system. This was a repeat violation from a previous FDA-483 that was issued to your firm.

Our inspection also revealed that your devices are misbranded within the meaning of 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 regarding the device that is required by or under section 519 of the Act, 21 U.S.C. § 360i, and 21 C.F.R. Part 803-Medical Device Reporting (MDR) regulation. More specifically, your firm failed to:

1. Develop, maintain, and implement an MDR procedure as required by 21 CFR § 803.17. Specifically, your firm lacks an adequate system for the effective identification, communication, and evaluation of events that may be subject to medical device reporting. This issue was discussed during a previous inspection at your firm.

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 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 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 violation(s), or similar violation(s), 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, Compliance Officer 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 violation(s) noted in this letter
and in the list of 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 violation(s), and take prompt actions to correct the violation(s) and to bring your products into compliance.

Sincerely yours,

/s/

Diana Amador Toro
District Director
New Jersey District Office