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Inspections, Compliance, Enforcement, and Criminal Investigations

Axis Health Care LLC



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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October 20, 2010

WARNING LETTER NO. 2011-NOL-02

United Parcel Service

DELIVERY SIGNATURE REQUESTED

Mr. William D. Henderson, President
axis Health Care, LLC
5755 Carmichael Parkway
Montgomery, Alabama 36117

Dear Mr. Henderson:

On May 18 - 21, 2010, U.S. Food and Drug Administration (FDA) investigators inspected your facility, located at 5755 Carmichael Parkway, Montgomery, Alabama and determined your firm manufactures the Picture Archive and Communication System (PACS). Under Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), [21 United States Code (USC) 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.

Our inspection and a review of our records revealed the PACS device is adulterated under Section 501(f)(1)(B) of the Act [21 USC 351(f)(1)(B)], because you do not have an approved application for premarket approval (PMA) in effect pursuant to Section 515(a) of the Act, 21 USC 360e(a), or an approved application for an investigational device exemption (IDE) under Section 520(g) of the Act, 21 USC 360j(g): The device is also misbranded under Section 502(o) of the Act, 21 USC 352(o), because you did not notify FDA of your intent to introduce the device into commercial distribution, as required by Section 510(k) of the Act, 21 USC 360(k). For a device requiring premarket approval, the notification required by Section 510(k) of the Act, 21 USC 360(k), is deemed satisfied when a PMA is pending before FDA, as required under Title 21, *Code of Federal Regulations*, Part 807.81(b) [21 CFR 807.81(b)]. The information you need to submit in order to obtain approval or clearance for your device is described on FDA's Internet website at <http://www.fda.gov/cdrh/devadvice/3122.html>¹. FDA will evaluate the information you submit and decide whether your product may be legally marketed.

This inspection revealed the PACS device is 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, 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 21 CFR 820. We received your response dated June 2, 2010, concerning our investigators' observations noted on the Form FDA 483, inspectional Observations, issued to you and we address this response below, in relation to each of the noted violations. These violations include, but are not limited to, the following

1. 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 PACS device.

Your response states your firm "...has control of the design of the device, but has not followed a formal procedure with documentation. We will implement and ensure specified requirements are met during all stages of product

development and implementation. ...A complete written, reviewed, and approved set of procedures and process implementation will be completed by: August 31, 2010...." We concluded your response is inadequate because your firm did not demonstrate it had implemented all elements for the design control requirements.

2. Failure to establish and maintain a Design History File (QHF) 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 820.300). For example, your firm failed to establish a DHF for the PACS device to demonstrate the device was developed in accordance with the approved design plan and design control requirements, as required by 21 CFR 820.30(j).

Your response states your firm "...included as Exhibit B are screen shot from our **(b)(4)** and an **(b)(4)** used to create design changes. Going forward axis Health Care will implement and record all records for the Design History File (DHF). ...A complete written, reviewed, and approved set of procedures and process implementation will be completed by: August 31, 2010...." We have reviewed your response dated June 2, 2010, and have concluded it is inadequate because your firm did not provide evidence of implementation to ensure the PACS device was developed according to design control requirements and met design specifications established by the firm.

3. Failure to establish and maintain adequate procedures for implementing corrective and preventive action (CAPA) in a uniform and consistent manner, as required by 21 CFR 820.100(a). For example, your firm failed to establish or implement a written CAPA procedure.

Your response states your firm "...practices corrective and preventive actions but has not followed a formal procedure with documentation. We will establish, document and implement a corrective and preventive action (CAPA) plan. This plan will address all of Section 820.100 of the FDA regulations. ...A complete written, reviewed, and approved set of procedures and process implementation will be completed by August 31, 2010...." We have reviewed your response dated June 2, 2010, and concluded it is inadequate because your firm did not provide evidence of implementation of the correction, corrective action, and proposed preventive action for the device.

4. Failure to establish and maintain adequate procedures for receiving, reviewing, and evaluating complaints by a formally designated unit, as required by 21 CFR 820.198(a). For example, your firm failed to maintain complete complaint records as required by the law. A review of 35 complaints from 2009 and 2010 revealed none of the records met the quality system requirements for complaint files because there was no documentation to show the complaints were investigated and what action was taken following the investigation of the complaints. Listed below is an example of this deficiency of the complaint handling system of your firm:

- A complaint received on May 20, 2009, for the PACS device states "...she tried merging a patient's studies...But now that she has done that there are no studies under the patient's profile." The problem resolution is documented as "...took care of the issue." There is no additional information maintained for this complaint.
- A complaint received on July 10, 2009, for the PACS device states"...Read Station is not allowing the user to lighten or darken images at window level ..they can't mark images as dictated..." The problem resolution is documented as "...took care of the issue." There is no additional information maintained for this complaint.
- A complaint received on January 19, 2010, for the PACS device states "... a study would not burn on a cc for a patient..." The problem resolution is documented as "...took care of the issue..." There is no additional information for this complaint.

Your response states your firm "...has evaluated customer complaints but has not followed a formal procedure with documentation. We will establish and implement quality procedures to document and evaluate customer complaints....A complete written, reviewed, and approved set of procedures and process implementation will be completed by August 31, 2010...." We have reviewed your response, dated June 2, 2010, and have concluded it is inadequate because your firm did not demonstrate implementation for receiving, reviewing, and evaluating complaints for the PACS device by a designated unit within the firm.

5. Failure to develop, conduct, control, and monitor production processes to ensure a device conforms to its specifications, as required by 21 CFR 820.70(a). For example, your firm failed to establish and implement written process control procedures, including standard operating procedure and work instructions to ensure the PACS device conformed to established specifications.

Your response states your firm "...has procedures in place but has not followed a formal procedure with documentation. We will identify and plan production operations, which directly affect quality to ensure production process, are carried out under controlled conditions....A complete written, reviewed, and approved set of procedures and process implementation will be completed by: August 31, 2010...." We have reviewed your response dated June 2, 2010, and have concluded it is inadequate because you did not provide evidence to ensure the PACS device conforms to your firm's specifications.

6. Failure to establish and maintain adequate procedures to control all documents, as required by 21 CFR 820.40. For example, your firm failed to demonstrate the device's instruction manual was approved prior to distribution to the end users.

Your response states your firm "...will implement and maintain document Data Control. ...The Quality Manager will oversee these policies, processes, and documentation. A complete written, reviewed, and approved set of procedures and process implementation will be completed by: August 31, 2010..." We have reviewed your response dated June 2, 2010, and have concluded it is inadequate because you did not provide evidence to demonstrate implementation of document approval, document distribution and document changes for PACS device.

7. Failure to maintain device master records (DMR's) and to ensure each DMR is prepared and approved in accordance with 21 CFR 820.40. The DMR for each type of device shall include, or refer to, the location of device specifications including appropriate drawings, composition, formulation, component specifications, and [software](#) specifications, as required by 21 CFR 820.181. For example, your firm failed to establish and maintain a DMR, including device specifications and requirements for installation, production process, quality assurance and packaging/labeling for the PACS device.

Your response states your firm "...does retain certain master records for the hardware and [software](#) as specified in each customer agreement. ...We do need to improve our record keeping as a Device Master Record (DMR) and will do so in accordance with the regulations offered by the investigators....A complete written, reviewed, and approved set of procedures and process implementation will be completed by: August 31, 2010..." We have reviewed your response dated June 2, 2010, and have concluded it is inadequate because your firm did not provide evidence to authenticate the performance and configuration characteristics established for the PACS device, its components, packaging, labeling, quality assurance program, production, installation, maintenance, and service to ensure these activities can be controlled.

8. Failure to establish and maintain adequate procedures to ensure Device History Records (DHR's) 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 PACS device.

Your response states your firm "...does maintain a log in our portal, of all computers shipped to clients, as well as, maintaining records of the respective [software](#) versions.

...axis Health Care does need to improve the written procedures and the comprehensive documentation necessary to meet all requirements for the Device History Record (DHR) at the batch level for all products delivered to the end user. ...A complete written, reviewed, and approved set of procedures and process implementation will be completed by: August 31, 2010..." We have reviewed your response dated June 2, 2010, and have concluded it is inadequate because you did not provide evidence of production history records for each PACS device manufactured by the firm.

9. 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.

Your response states your firm " did conduct reviews but has not followed a formal procedure with documentation The Vice President of Operations will oversee these policies, processes, and documentation. A complete written, reviewed, and approved set of procedures and process implementation will be completed by: August 31, 2010...' We have reviewed your response dated June 2, 2010, and have concluded it is inadequate because you did not provide evidence of implementation for the reviews of the quality system for the PACS device at defined intervals

10. Failure to establish and maintain adequate 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. Quality audits shall be conducted by individuals who do not have direct responsibility for the matters being audited, as required by 21 CFR 820.22. For example, your firm failed to conduct quality audits as a manufacturer of a medical device. In addition, your firm failed to develop, maintain, and implement written quality audit procedures.

Your response states your firm "...will establish and document procedures to audit the effectiveness of the quality system....A complete written, reviewed, and approved set of procedures and process implementation will be completed by: August 31, 2010..." We have reviewed your response dated June 2, 2010, and have concluded it is inadequate because you failed to provide evidence to demonstrate your firm is conducting quality audits which describe the procedures used to establish, maintain, and conduct audits to ensure adequacy and compliance with quality system requirements for the PACS 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 axis Health Care employee involved in manufacturing, complaint and Medical Device Reporting (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.

Your response states your firm "...has provided training to employees necessary to perform their respective duties. We have held lunch and learn meetings complete with training and post training testing as one example.

Our documentation of such training is lacking....A complete written, reviewed, and approved set of procedures and process implementation will be completed by: August 31, 2010..." We have reviewed your response dated June 2, 2010, and have concluded it is inadequate because you did not provide evidence to demonstrate the establishment of an employee training program in compliance with FDA requirements for manufacturing medical devices.

Our inspection revealed the PACS device is misbranded under Section 502(t)(2) of the Act, 21 USC 352(t)(2), because you failed or refused to furnish material or information with respect to the device which is required by or under Section 519 of the Act, 21 USC 360i, and 21 CFR 803 MDR regulation. Significant deviations include, but are not limited to, the failure to develop, maintain, and implement written MDR procedures, as required by 21 CFR 803.17. For example, your firm failed to develop, maintain and implement MDR procedures as a manufacturer of a medical device.

Your response states your firm " ...is in the process of developing a documented Medical Device Reporting System. " ...This will be an ongoing review. Initial written, reviewed, and approved procedures to be completed by: August 31, 2010..." We have reviewed your response dated June 2, 2010, and have concluded it is inadequate because you did not submit written MDR procedures. Since your firm has failed to establish or implement the QS procedures required by 21 CFR 820, your device is in violation of these regulations.

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. 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, PMA applications for Class III devices to which the QS 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 any additional, 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 additional corrective action you have taken to include procedures, examples of DMR's and DHR's, complaint follow-up documentation, etc. 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.

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 Form FDA 483 Inspectional Observations, 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 to bring your products into compliance.

Your response should be sent to Cynthia R. Gibson, Compliance Officer, U.S. Food and Drug Administration, at the above address. If you have any questions about the content of this letter, please contact Ms. Gibson at (251) 344-8208, extension 105.

Sincerely,

/S/

H. Tyler Thornburg
District Director
New Orleans District

Links on this page:

1. <http://www.fda.gov/cdrh/devadvice/3122.html>