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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

Chicago District
550 West Jackson Blvd., 15th Floor
Chicago, Illinois 60661
Telephone: 312-353-5863

August 12, 2008

WARNING LETTER
CHI-4-08

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Vishal K. Wanchoo
President and CEO
GE Healthcare Integrated IT Solutions
540 W. Northwest Highway
Barrington, Illinois 60010-3051

Dear Mr. Wanchoo:

During an inspection of your firm located in Barrington, Illinois, from April 15 – May 13, 2008, an investigator from the Food and Drug Administration (FDA) determined that your firm manufactures and distributes Centricity Imaging and other Picture Archiving and Communication System (PACS) products. Under Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. 321(h)], these products are defined as medical 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 (CFR), Part 820. We received your response dated June 2, 2008, concerning our investigator's observations noted on the FDA-483, List of Inspection Observations, which was issued to your firm on May 13, 2008. We address this response below, in relation to each of the noted violations, where appropriate. These violations include, but are not limited to, the following:

1. Failure to establish and maintain adequate procedures for 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).

For example:

a. Your CAPA procedures do not identify all CAPA data sources or define the requirements for analyzing and evaluating those data sources. Examples of data sources not included are: Complaint Handling Access Database (CHAD) complaints, Service data, and System Performance Reports (SPRs).

b. Your CAPA procedures do not address obtaining and reviewing information from other GE Healthcare sites that share the same product components (such as shared software code). In October 2007, GE Medical Systems in France submitted a correction and removal report for safety issues identified in their Advantage Workstation (AW) product. The evaluation of the same safety issues identified in the GE Healthcare IITS AW Suite version 2.0.1 product (which builds on the AW software code) did not include the consideration that the site in France initially reported these issues.

We have reviewed your response and have concluded that your response is inadequate. Your response states that you will conduct a retrospective review of all available functional area trend analysis from all relevant quality data sources over the past two years (June 2006 to May 2008) to identify potential issues requiring escalation to CAPA. The review was to be completed by July 31, 2008. Please submit the retrospective review for our review.

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

For example:

a. The AW Suite 2.0 System Requirements Specification has not been updated to reflect the Volume Viewer Advanced Vessel Analysis requirement to display a message when PET slices are missing from a loaded dataset. This issue was identified in Software Problem Report 64263 and a design change was implemented in AW Suite 2.0.1, released in October 2007. The issue was originally identified at GE Medical in France in a product with a shared code base (Advantage Workstation -AW). The Software Requirements Specification for the AW product was updated in September 2007; however, this design change was not identified or implemented for the AW Suite 2.0.

b. Release notes for Centricity PACS version 3.0.4 and 2.1.5.5 include incorrect references to complaints that were fixed. For example, the issue of incorrect patient jackets intermittently opening is listed in the section of identified problems that are not fixed (complaint 13092353). The project plan and verification for this issue shows that the fix is included in 3.0.4 and 2.1.5.5.

We have reviewed your response and have concluded that your response is inadequate. Your response states that you will conduct a retrospective review of all releases in the past two (2) years (June 2006 to May 2008) for PACS and Perinatal software products to ensure that documents required by the design change plan were released and that customer Release Notes accurately reflect the changes implemented in the release(s). You state the review will be completed by August 31, 2008. Please submit the retrospective review for our review.

3. Failure to establish and maintain adequate procedures for finished device acceptance to ensure that each production run, lot, or batch of finished devices meets acceptance criteria, as required by 21 CFR 820.80(d).

   For example, manufacturing procedures do not include a requirement for conducting and documenting acceptance activities for CD/DVD burns and eDistribution downloads to ensure that the software matches the engineering master files.

   We have reviewed your response and have concluded that your response is inadequate. Your response states that you will conduct a retrospective review of manufacturing acceptance activities to verify production and electronic distribution (eDistribution) mechanisms of all current production versions, maintenance releases, service packs, and software patches against the master media serviced through Barrington manufacturing. The review was to be completed by July 31, 2008. Please submit the retrospective review for our review.

4. Failure to establish and maintain adequate procedures for the information that must be documented in a record of the investigation, as required by 21 CFR 820.198(e).

   For example:

   a. The following complaints are incomplete and do not include an investigation plan, investigation results, investigation updates or the identification or implementation of corrections or corrective actions:

      i. Compliant 1314915 was opened on November 16, 2007, because a customer on [redacted] stated that CT exam reports were being assigned to incorrect exams. On 1/9/08, the complaint evaluation risk assessment resulted in an R2 rating (Product Safety issue) and a work around was created for the customer. The CAPA Review Board reviewed the issue March 7, 2008, and decided a CAPA was not necessary. An investigation to identify root cause was not conducted until information about the complaint investigation was requested during this inspection. Information provided on 5/1/08 revealed that a fix for this issue

was made in April 2005. Mandatory Safety Field Modification Instruction (FMI) 85122 was created on 5/12/08 for this issue.

ii. The investigation into two downloads of the CA1000 Spa12 code reported as different (complaint 13154048) was assigned on Dec. 16, 2007, and due April 30, 2008. The investigation decision rationale states there is a possible media release issue. The complaint investigation does not include an investigation plan, investigation results, investigation updates or the identification or implementation of corrections or corrective actions. An investigation into this issue was not initiated until information related to this complaint was requested during this inspection.

b. Your investigation procedures do not include the Support Central Case system through which technicians and engineers document on-going investigations of service records and complaints.

Your response appears to be adequate. Your response states that you have revised the IITS Investigation Work Instruction (DOC0350062). The complaint handling unit personnel were trained to ensure that complaints are not closed until there is a completed investigation or, if applicable, a documented rationale for why an investigation is not required. You also revised the IITS Complaint Handling Work Instruction (DOC0350060). A final review has been established to assure all complaints have been properly investigated and documented. Training on the new procedures was conducted and training records were provided. We will verify the adequacy of this correction at our next inspection.

5. Failure to maintain adequate procedures for receiving, reviewing, and evaluating complaints by a formally designated unit, as required by 21 CFR 820.198(a).

For example, complaint handling procedure titled '[redacted]' was not followed with regard to obtaining more information or further evaluating perinatal product service records with complaint status of 'Unknown'. The Perinatal Service Record Complaint Status in the 2007 quarter 4 management review shows 570 records identified as Unknown (3,377 records were identified as non-complaints and 632 records were identified as complaints).

Your response appears to be adequate. Your response states that you have revised the IITS Complaint Handling Access Database (CHAD) , DOC0417335, to provide guidance for re-evaluation on a periodic basis of the CHAD database event records that contain insufficient information needed to make a complaint determination to

ensure timely and effective follow-up. You have also revised your IITS Siebel Service Record Complaint Review procedure, DOC0350068, to provide guidance for re-evaluation on a periodic basis of the Siebel database event records that contain insufficient information needed to make a complaint determination to ensure that effective follow-up is implemented to make a complaint determination. Product specific service system work instructions were modified to enhance timeliness and completeness of service records. Work Instructions and CASE Workflow and CPN Service Management were modified to further facilitate complaint evaluation, MDR determination and the potential safety impact of service data. Training was conducted for these specific procedural modifications and training records were provided. We will verify the adequacy of this correction at our next inspection.

The inspection also revealed that your Centricity Imaging 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 CFR Part 803 – Medical Device Reporting (MDR) regulation, and 21 CFR Part 806 – Reports of Corrections and Removals regulation. Significant deviations include, but are not limited to, the following:

6. A MDR report was not submitted within 30 days of receiving or otherwise becoming aware of information that reasonably suggest that marketed device has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur, as required by 21 CFR 803.50(a)(2).

   For example, complaint 13116009 was not submitted as a MDR. In accordance with comment 12 of the preamble to the MDR regulation, "A malfunction is reportable if any one of the following is true...(5) the manufacturer takes or would be required to take an action under section 518 or 519(f) [redesignated 519(g) by 110 P.L. 85, Sec. 226 (Sept. 27, 2007)] of the Act as a result of the malfunction of the device or other similar devices." 60 Fed. Reg. 63578, 63585 (Dec. 11, 1995). Your July 20 and August 2, 2007, correction correspondences regarding the software malfunctions for the Centricity Perinatal Systems have been classified as a Class II recall, Z-2037-2008, and is considered a section 519(g) action.

7. Failure to adequately maintain a MDR event file as part of your complaint file, as required by 21 CFR 803.18(e). For example, your MDR event file for complaint 13116009 did not document an explanation of why you did not submit a MDR report as well as the results of your evaluation of this event.

8. Failure to conduct an investigation and evaluate the cause of each event, as required by 21 CFR 803.50(b)(3). For example, complaint 13092353 did not include documentation of an investigation into a patient misdiagnosis which occurred after an incorrect patient jacket opened on the Centricity PACS workstation and did not determine if it represents a MDR reportable event.

9. Failure to develop, maintain, and implement adequate written MDR procedures, as required by 21 CFR 803.17. For example, the initial decision not to report a MDR for several complaints conflicts with your firm's complaint evaluation risk assessment which lists a severity rating of 2 "Defect has caused or has potential to cause serious injury" and a final rating of R2, "This complaint has been evaluated as a Product Safety issue..." You did not implement your procedure for determining when an event meets the criteria for MDR reporting.

   We have reviewed your response and have concluded that your response is inadequate. You will be conducting a retrospective review of all complaint records for the past 2 years (June 2006 to May 2008) associated with PACS and Perinatal to re-evaluate MDR reportability for adverse events or reportable malfunctions. The review will be completed by August 31, 2008. Please submit the retrospective review for our review.

10. Failure to submit a written report to FDA of any correction or removal of a device initiated by such manufacturer or importer to remedy a violation of the act caused by the device which may present a risk to health, as required by 21 CFR 806.10(a)(2). For example, your correction to apply a software patch for the Centricity Perinatal Monitoring System problem of non-identifiable patient information being added to an incorrect file was not reported to FDA. A letter describing this issue was sent to customers on July 20, 2007, and patches are available beginning in August 2007.

11. Failure to submit a written report (within 10 days) to FDA of any correction or removal of a device initiated by a manufacturer, as required by 21 CFR 806.10(b).

    For example:

    a. Correction and Removal report 3004526608-4/17/08-002-C for AW Suite version 2.0.1 was reported to FDA on April 21, 2008, although AW Suite 2.0.1 was approved for release in October 2007. A notification to customers regarding the safety issues corrected in AW Suite version 2.0.1 was not issued at the time of release. The safety issues included Advanced Vessel Analysis (AVA) incorrect tracking and measurement and AVA measure not updated after editing the centerline.

b. Correction and Removal report 3004526608-05/06/08-003-C was reported to FDA on May 6, 2008, for a patient safety issue involving incorrect study date and time information being displayed in the Centricity PACS software. The Field Modification Instruction (FMI) Development and Deployment Plan for this issue was approved as a Mandatory Safety FMI in December 2007.

12. Failure to keep a record of justification for not reporting the correction or removal action to FDA, as required by 21 CFR 806.20. For example, your correction to apply a software patch for the Centricity Perinatal Monitoring System problem of non-identifiable patient information being added to an incorrect file was not reported to FDA. There was no justification in the record for why this correction was not reported to FDA.

    We have reviewed your response and have concluded that your response is inadequate. Your response states that you will conduct a retrospective review of product releases (e.g., patches, maintenance releases, service packs, new product introduction) distributed to the field for PACS and Perinatal products over the past 2 years (June 2006 to May 2008) to determine if there are additional field actions that should have been reported to FDA as Corrections and Removals and were not. The review will be completed by August 31, 2008. Please submit the retrospective review for our review.

You should take prompt action to correct these deviations and to establish procedures to prevent their recurrence. Failure to promptly correct these deviations may result in FDA initiating regulatory action without further notice, including but 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 of receipt of this letter of the specific steps you have taken to correct the violations, including:

- An explanation of your plan to prevent these violations from recurring.
- Any documentation of the corrective actions you have taken.

- An explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur.
- A timetable for implementation of corrective actions. If they will not be completed within 15 working days, state the reason for the delay and the timetable for completing the corrective actions.

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 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.

Please address your written response to Lorelei Jarrell, Compliance Officer, Food and Drug Administration, 550 W. Jackson Blvd., 15th floor, Chicago, IL 60661. If you have any questions about the content of this letter, please contact Ms. Jarrell at 312-596-4216.

Sincerely,

Scott J. MacIntire
District Director