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APR 10 2001

WARNING LETTER

Food and Drug Administration  
Center for Devices and  
Radiological Health  
2098 Gaither Road  
Rockville, MD 20850

VIA FEDERAL EXPRESS

Mr. Reinaldo Garcia  
President & CEO  
GE Medical Systems, Inc. SA  
283 rue de la Miniere BP 34  
78533 Buc Cedex  
FRANCE

Dear Mr. Garcia:

We have reviewed the results of the Food and Drug Administration (FDA) post PMA (# [REDACTED]) inspection of your manufacturing facility located in Buc Cedex, France on December 4-8, 2000, regarding the Full Field Digital Mammography System, Senographe 2000D. This is a device as defined by section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act). At the conclusion of the inspection, the Food and Drug Administration (FDA) investigator issued a FDA 483, Inspectional Observations.

The above-stated inspection revealed that this device is adulterated under section 501(h) of the Act, in that the methods used in, or the facilities or controls used for the manufacturing, packing, storage, or installation are not in conformance with the Quality System Regulations (QS) for Medical Device Regulations, as specified in Title 21, Code of Federal Regulations (21 CFR), Part 820 as listed below: Your responses, dated January 16, 2001 and February 8, 2001, to the investigator's findings were also reviewed. We have the following comments:

1. Failure to establish and maintain procedures to ensure that the design requirements relating to a device are appropriate and address the intended use of the device, including the needs of the user and patient. The procedures shall include a mechanism for addressing incomplete, ambiguous, or conflicting requirements. The design input requirements shall be documented and shall be reviewed and approved by a designated individual(s). The approval, including the date and signature of the individual(s) approving the requirements, shall be documented as required by 21 CFR 820.30(c). For example, design control input failed to assure 2 spot compression

paddles (round and square) met the 1 percent of Source-image receptor distance (SID) MQSA/FDA requirement. An USA complaint [REDACTED] dated July 2000 documented failure during installation. Field upgrade FMI [REDACTED] was implemented to update all units in the field.

Your response is not adequate. Please provide a copy of the completed FMI [REDACTED]. Provide evidence of implementation of the [REDACTED] ( [REDACTED] [REDACTED] [REDACTED] [REDACTED] System) software tool. Provide documentation of the completion of employee training for the [REDACTED] software tool and design controls promised by February 2001. This information is necessary so that a final determination of your corrections can be assessed.

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, MDR/Complaint [REDACTED] submitted in November 2000 for broken cables on the Omega 4 table system. The complaint indicated vibration/shock. A design change was implemented in November 1998 to correct the problem. Nine (9) complaints have been received since the 1998 design change was implemented. A failure analysis is in process to re-address the issue.

Your response is not adequate. Please provide the following documents and/or evidence of implementation as applicable:

- Fail-Safe design solution - promised by February 28, 2001
- Reliability Models- completed and those promised completed by March 31, 2001
- [REDACTED] [REDACTED] [REDACTED] - training documentation and [REDACTED] training schedule promised by March 2001.
- FMI [REDACTED]

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. Finished devices shall be held in quarantine or otherwise adequately controlled until released. Finished devices shall not be released for distribution until: (1) the activities required in the DMR are completed; (2) the associated data and documentation is reviewed; (3) the release is authorized by the signature of a designated individual(s); and (4) the

authorization is dated as required by 21 CFR 820.80(d). For example, approximately seven Senographe 2000D detectors failed incoming inspection between May-November 2000 and were shipped to the supplier ( [REDACTED] ) for failure analysis. The failures were "DOA" (failure to meet specifications) type failure. Complaint [REDACTED] and [REDACTED] document detectors shipped to customers in the field that arrived DOA/without meeting specifications.

Your response is not adequate. Please respond as follows:

- (1) FNC [REDACTED] and FNC [REDACTED] - please provide English translation of [REDACTED] Inspection document.
- (2) FNC [REDACTED] and [REDACTED] - Provide evidence of the 200 hour power burn-in and screening of detectors in inventory.
- (3) Provide evidence of implementation of the [REDACTED] Form ( [REDACTED] )
- (4) Customer Complaint (CQA) - [REDACTED] - please provide English translation of [REDACTED], Incoming procedure.

3. Failure to establish and maintain adequate acceptance procedures, where appropriate, to ensure that specified requirements for in-process product are met. Such procedures shall ensure that in-process product is controlled until the required inspection and tests or other verification activities have been completed, or necessary approvals are received, and are documented as required by 21 CFR 820.80(c). For example, Senographe 2000D incoming product was not adequately inspected or tested to verify conformance to specifications. Specifically,

- a. 33 Monitors failed during in process testing from May-November 2000. 25 of these 33 failures were "DOA" type failures (failure to meet specifications).
- b. 15 Buck's failed during in process testing from May-November 2000. 12 of the 15 failures were "DOA" type failures (failure to meet specifications).
- c. 10 Chiller conditioners failed during in process testing from May-November 2000. 7 of the 10 were "DOA" type failures. Complaint [REDACTED] dated August 2000 documented a chiller/conditioner failure DOA (failure to meet specifications) in the field/customer site.

Your response is not adequate. Please provide documentation regarding the new [REDACTED] action process i.e., FNC system query promised by February 28, 2001, weekly review process for repetitive defects promised by January 31, 2001, decision tree and updated procedures promised by March 9, 2001, and training documentation of employees of the [REDACTED] process and procedures promised by March 23, 2001. Also, please respond as follows:

- Regarding item a. - Please provide the English translation of Test Instruction [REDACTED] copy of validation plan for monitors with new supplier and a copy of Quality Plan with the new supplier promised by April 16, 2001.
- Regarding item b. - Please provide the English translation of Test work Instructions [REDACTED] and [REDACTED]. Provide documentation of completion of investigation for audible noise defect and/or final results.
- Provide training documentation of supplier auditors trained under the new system [REDACTED] Audit tracking software. Also, provide a copy of the new procedure for the audit management software.

5. Failure to follow established procedures for implementing corrective and preventive action and failure to document all activities, and their results, as required by 21 CFR 820.100(a) and (b). For example, the firm failed to determine Correction/Removal FMI [REDACTED] for compression paddles exceeding beyond 1% of SID (MQSA/FDA requirement). The Safety FMI [REDACTED] met requirement for evaluation for reportability for 21 CFR 806, per the firm's Correction/Removal Procedure [REDACTED] pages [REDACTED]

Your response may be adequate. Please provide a copy of your validated FMI [REDACTED], promised completion by February 2001. During the inspection, on December 5, 2000, you completed your risk assessment for FMI [REDACTED], after receiving the complaint in July 2000.

6. Failure to establish and maintain adequate procedures for implementing corrective and preventive action as required by 21 CFR 820.100(a). For example, Correction and Removal procedure [REDACTED] fails to assure that both Class I and Class II Recalls be reported to the FDA. Specifically, the decision process on page [REDACTED] of the procedure (used to make the

reportability decision) fails to meet requirements in [REDACTED] of the procedure.

Your response appears to be adequate.

7. Failure to assess and determine whether service reports that may represent an event which must be reported to FDA under 21 CFR part 803 be automatically considered complaints and process them in accordance with the requirements of Sec. 820.198 as required by 21 CFR 820.200(c). For example, Field Service procedure [REDACTED] fails to require field service records be reviewed for MDR reportable events.

Your response appears to be adequate.

8. Failure to ensure that device packaging and shipping containers are adequately designed and constructed to protect the device from alteration or damage during the customary conditions of processing, storage, handling, and distribution as required by 21 CFR 820.130. For example, shipping vibration testing and vibration validation was not conducted for Apollo detector shipping container released in July 2000 [REDACTED]. No justification for lack of validation exists.

Your response appears to be adequate.

The letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the form FDA 483 issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the Food and Drug Administration. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

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.

Please notify this office within 15 working days of receipt of this letter of the specific steps you have taken, or intend to take, to correct the noted violations, including an explanation

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of each step being taken to prevent the recurrence of similar violations. 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. Please include any and all documentation to show that adequate corrections have been achieved. In the case of future corrections, an estimated date of completion, and documentation showing plans for correction, should be included with your response to this letter.

If the documentation is not in English, please provide a translation to facilitate our review.

Your response should be sent to the Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Division of Enforcement I, Diagnostic Devices Branch, HFZ-322, 2098 Gaither Road, Rockville, Maryland 20850, to the attention of Ms. Fleadia Farrah.

Sincerely yours,

A handwritten signature in black ink, appearing to read "L. D. Spears". The signature is stylized and includes a small flourish at the end.

Larry D. Spears  
Acting Director  
Office of Compliance  
Center for Devices and  
Radiological Health