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Food and Drug Administration
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December 27, 2002

WARNING LETTER

CERTIFIED MAIL

RETURN RECEIPT REQUESTED

Mr. Gerald D. Knudson
President and CEO
Fischer Imaging Corporation
12300 N. Grant Street
Denver, Colorado 80241

Ref. #: DEN-03-09

Dear Mr. Knudson:

On August 21 – September 9, 2002 Investigator Nicholas R. Nance of our office conducted an inspection of Fischer Imaging Corporation, Denver, CO. Our investigator determined that your firm manufactures various products, including digital mammography systems. These products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above stated inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Quality System/Good Manufacturing Practice (QS/GMP) for Medical Devices Regulations, as specified in Title 21, Code of Federal Regulations (21 CFR), Part 820. The deviations are as follows:

1. Complaint handling procedures for receiving, reviewing, and evaluating complaints have not been fully implemented as required by 21 CFR 820.198(a). Specifically, reports of malfunctions of SenoScan digital mammography systems from customer/user sites were not considered to be, or reported as, complaints. Additionally, reports of malfunctions lacked sufficient event information to allow for adequate complaint evaluation or Medical Device Report (MDR) applicability.
2. The procedures for establishing and maintaining corrective and preventive actions were not fully implemented as required by 21 CFR 820.100(a). Specifically, Fischer

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corrective action procedures were not being followed for Product Change Orders (PCO) requiring design or software changes to in-house and/or released units. PCOs lacked documentation of, or reference to, risk assessment or priority, justification of the "scope" classification, corrective action requests (CAR), component product reports (CPR) and/or technical service bulletins (TSB), as required by the procedures.

3. Corrective and preventive actions have not been verified or validated to ensure that the action is effective and does not adversely affect the finished device as required by 21 CFR 820.100(a)(4). Specifically, design changes were being validated/verified on ~~XXXX~~ systems (~~XXXXXX~~), that lacked documentation to assure the systems were representative or adequate for use.
4. Procedures for addressing the evaluation of nonconforming product were not complete as required by 21 CFR 820.90(a). Specifically, nonconformance reports of ~~XXXX~~ component and system defects and malfunctions did not include a determination of the need for an investigation.
5. Procedures that describe the review and disposition process for nonconforming product were not implemented as required by 21 CFR 820.90(b). Specifically, the nonconformance (CPR) database lacked required information including location codes and failure codes. Additionally, other sources used to evaluate nonconforming product, including reports of malfunctions at installation, lacked information required by nonconformance reporting procedures.
6. The device history record does not include complete acceptance records that demonstrate the device is manufactured in accordance with the device master record as required by 21 CFR 820.184(d). Specifically, review of device history records found incidents of lack of required approvals and traceability identification, unauthorized changes in test data and incorrect revision numbers.
7. Procedures for acceptance or rejection of incoming product were not implemented as required by 21 CFR 820.80(b). Specifically, records covering the printed circuit board ~~XXXXXX~~ test were being discarded.
8. Incoming product was not adequately inspected or tested to verify conformance to specifications as required by 21 CFR 820.80(b). Specifically, redesigned/revised components and components from new manufacturers were being accepted for use without the performance of a first article inspection, as required by Fischer procedures.
9. Certain inspection and testing equipment is not suitable for its intended purposes or capable of producing valid results as required by 21 CFR 820.72(a). Specifically, manufacturing, inspection and testing procedures were being used that were not formally approved in accordance with Fischer document control procedures.

The above-identified deviations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that your establishment is in compliance with all

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requirements of the Federal regulations. The specific violations noted in this letter and in the Form FDA-483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your establishment's quality system. You are responsible for investigating and determining the causes of the violations identified by the FDA. You also must promptly initiate permanent corrective and preventive action on your Quality System.

We acknowledge receipt of your September 9, and October 7, 2002 responses to the FDA-483, and updates of October 21, November 4 and November 22, 2002. Your responses fail to address the actions you have taken or will take regarding the significant number of field failures and malfunctions and subsequent field corrective actions, including rework and retrofits, to SenoScan digital mammography systems distributed since the PMA was approved in September, 2001. In addition, numerous, and in some cases significant, design and or software changes have been made that required both in-house and or field corrective actions since the approval. We are not aware of any PMA supplements submitted for the SenoScan system since the PMA was approved.

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, no premarket submissions for Class III devices to which the QS/GMP deficiencies are reasonably related will be cleared until the violations are corrected. Also, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

You should notify this office in writing within fifteen (15) working days of receipt of this letter of any other additional steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within fifteen (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 H. Tom Warwick, Compliance Officer, Food and Drug Administration, Denver District, P. O. Box 25087, Denver, CO 80225-0087. If you have any further questions, please feel free to contact Mr. Warwick at (303) 236-3054.

Sincerely,

Belinda Collins, Acting D.D. for

B. Belinda Collins
District Director

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