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NYK-1999-2



DEPARTMENT OF HEALTH & HUMAN SERVICES

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New York District

Food & Drug Administration
850 Third Avenue
Brooklyn, NY 11232

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

October 9, 1998

Mr. David Vozick
Chairman
AFP Imaging Corporation
250 Clearbrook Road
Elmsford, New York 10523

Ref.: NYK-1999-2

Dear Mr. Vozick:

During an inspection of your firm located in Elmsford, NY, conducted between the dates of July 14 and August 11, 1998, our investigator determined that your firm manufactures the SENS-A-RAY 2000, a dental imaging system. The SENS-A-RAY is a device 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 current good manufacturing practice, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to establish and maintain an adequate design change procedure as required by 21 CFR 820.30 (i). For example, the "Design Release and Changes" Procedure No. 9.3, Rev.6, dated 4/22/97, does not adequately address how all design control requirements will be satisfied or to what point in the design control process the change should be processed.
2. Failure to ensure that corrective and preventive action activities taken are adequately documented as required by 21 CFR 820.100(b). For example, the changes to the sensor circuit board were not adequately documented.
3. Complaint investigation records fail to always include the nature and details of the complaint, the results of the investigation, any corrective action taken, and any reply to the complainant as required by 21 CFR 820.198(e). Field Service Work Orders are not always completed. For example: #'s 10233, and 10313 include no entries under "reported problem"; #'s 10038, and 10037 include no entries under "actual problem" and "action taken"; #'s 10150, 10231, 10339,

and 10064 include no entry under "actual problem".

4. Failure to establish and maintain a procedure for the evaluation of complaints to determine if they represent a Medical Device Reporting event as required by 21 CFR 820.198(a)(3).

5. Failure to document and account for the disposition of all reworked sensors as required by 21 CFR 820.90(b).

6. Failure to document acceptance activities as required by 21 CFR 820.80(e). Records of electrical continuity testing and hypot testing are not maintained.

7. Failure to establish and maintain adequate procedures for the acceptance of incoming product as required by 21 CFR 820.80(b):

a. No procedure is established for inspecting or testing grabber boards, and vendor certificates received do not report whether the product passed or failed according to defined acceptance criteria.

b. Connector boards and sensor circuit boards were not inspected to assure that specifications were met.

8. Failure to establish process controls as required by 21 CFR 820.70, that include documented instructions for the assembly of the x-ray shield backing for the 448 charge couple device.

9. Failure to document calibration results for test equipment, such as, oscilloscopes, video generators, and hypot testers, to ensure that accuracy and precision limits are met as required by 21 CFR 820.72.

This 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 FDA 483 issued at the close out 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 FDA. 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. Additionally, no premarket submissions for devices to which GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates For Products For Export will be approved until the violations related to the subject devices have been corrected.

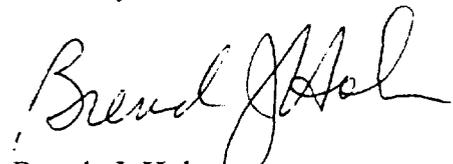
AFP Imaging Corp.
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You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include,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

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 noted violations, including 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. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which corrections will be completed.

Your response should be sent to Laurence D. Daurio, Compliance Officer, Food and Drug Administration, 850 Third Avenue, Brooklyn, New York 11232. If you have any questions, Mr. Daurio's telephone number is 718-340-7000 x 5708.

Sincerely,



Brenda J. Holman
District Director