



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region *m22167*

Food and Drug Administration  
Waterview Corporate Center  
10 Waterview Blvd., 3rd Floor  
Parsippany, NJ 07054

Telephone (973) 526-6007  
November 25, 1998

WARNING LETTER

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Ms. Sally Walsh, Owner  
Andrews & Walsh X-Ray  
55 Cannonball Road  
Pompton Lakes, New Jersey 07442

Dear Ms. Walsh:

FILE NO.: 99-NWJ-05

On October 28, 1998, FDA performed a field test of a certified diagnostic x-ray system which your firm assembled on June 6, 1998 according to Report of Assembly of a Diagnostic X-ray System, Form 2579 (D#337037). We tested this system to determine its compliance with portions of the Performance Standard for Diagnostic X-ray Equipment (Title 21, Code of Federal Regulations (CFR), Sections 1020.30-32). Diagnostic x-ray equipment are devices as defined by Section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act). This field test, Test ID #GI40408, was performed at:

[REDACTED]

Control Manufacturer: Tingle X-Ray  
Control Model Number: 525 SFQ  
Control Serial Number: 20217  
Room Number: X-Ray

While conducting our field test, we determined that the system was defective in the following manner:

Upon depressing the prep button, the x-ray system initiated x-ray exposure without activation of the exposure button [21 CFR 1003.2(b)(1)&(2)].

In addition to the above problem, our analysis of the field test data indicates that the system does not comply with the following item of the performance standard:

The x-ray field and undertable centers misalignment was 11.5% of the SID (source-to-image receptor distance). This exceeds the limit of up to 2% of the SID allowable by 21 CFR 1020.31(e)(1).

We request that you, as the responsible assembler, immediately investigate the deviations from the performance standard cited above in accordance with 21 CFR 1003 and 1004 as follows:

1. If you determine that improper assembly or installation causes the deviations and/or defects, you must correct it and/or the defects at no charge to the user by repairing the system, replacing it, or refunding the cost.
2. If you determine that the factory-based manufacturer causes the deviations and/or defects, you must notify it of the noncompliance and/or defects and send documentation of such notification to this office.
3. If you can establish that the system is compliant, that the alleged deviations or defects do not exist or do not relate to the safety of the product, or are directly attributable to user abuse or lack of maintenance, you may submit such evidence in accordance with 21 CFR 1003.30 within 15 working days of receipt of this letter.

Please note that improper installation, including failure to follow installation instructions, which cause the system to be noncompliant with the Performance Standard, may cause the system to be adulterated. Under Section 501(c) of the Act, the system would not be of a quality represented by the labeling (including the certification statement).

Failure to promptly correct these violations can result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include seizure and/or injunction and/or the imposition of civil penalties as provided for in Section 539 of the Act. Persons violating Section 538 of the Act are subject to civil penalties of up to \$1,000 per violation and up to a maximum of \$300,000.

You must report the results of your investigation and follow-up actions to this office within 15 working days of receipt of this letter. Your response should include the date that the corrective action was completed, the specific steps you have taken to correct the noted violations, an explanation of each step taken to prevent the recurrence of similar violations, and copies of service records and/or other supportive documents.

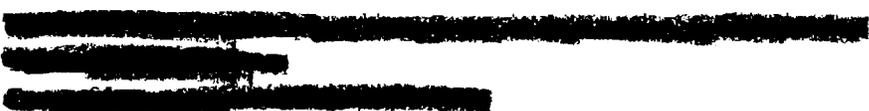
If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. If you do not respond within 15 working days, the FDA may consider you to be in violation of the Act, Sections 538(a)(2) and 538(a)(4) of Subchapter C - Electronic Product Radiation Control (formerly the Radiation Control for Health and Safety Act of 1968). Your response should be sent to the U.S. Food and Drug Administration, New Jersey District Office, 10 Waterview Blvd., Parsippany, New Jersey 07054, Attn: Rosa Brown, Compliance Technician.

If you have any questions regarding this letter, please feel free to call Toniette Williams, X-Ray Auditor at (973) 526-6018.

Sincerely yours,



DOUGLAS I. ELLSWORTH  
District Director  
New Jersey District Office,

Cc: 

NJ Dept. of Environmental Protection  
Bureau of Radiological Health  
CN 415  
Trenton, New Jersey 08625-0415

RLB/

Encl.: Field Test Report GI40408