



Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

PURGED *PK*

May 29, 1998

cc: HFI-35/FOI Staff
DWA

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 98 - 32

Steven J. Miller
President
Northern X-Ray Company
2118 Fourth Avenue South
Minneapolis, Minnesota 55404

Dear Mr. Miller:

On April 2, 1998, the State of North Dakota (under contract with the Food and Drug Administration [FDA]) conducted field test #AR54518A, of a certified diagnostic x-ray system which your firm assembled on August 28, 1997. The installation data is per "Report of Assembly of a Diagnostic X-ray System (FDA-2579) bearing number D308530. The system was tested to determine its compliance with portions of the Federal Performance Standard for Diagnostic X-ray Equipment (Performance Standard), Title 21, Code of Federal Regulations, Parts 1020.30-32 (21 CFR 1020.30-32). Diagnostic x-ray equipment is further defined as a medical device per Section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

User Site:

[REDACTED]

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Steven J. Miller
May 29, 1998

X-ray Control Manufacturer:


Model 36600G, serial V-2342

This letter confirms our telephone notification on May 27, 1998, to Mr. Jim Lyons of your firm regarding a serious non-compliance with the performance standard and our request that you immediately correct this violation.

Class A Non-compliance:

During compliance testing of the system, the system failed to terminate exposure on two occasions. As such, the system failed to meet 21 CFR 1020.31(a)(2) of the x-ray performance standard.

We request that you, as the responsible assembler, immediately investigate the above noted deviation in accordance with 21 CFR 1003 and 1004 as follows:

1. If you determine that the deviation or defect is caused by improper assembly or installation, you must correct it at no charge to the user by either repairing the system, replacing it or refunding the cost.
2. If you determine that the deviation or defect is caused by the factory-based manufacturer, you must notify them of the non-compliance and/or defect and send documentation of such notification to this office.
3. If you can establish that the system is compliant, that the alleged deviation or defect does not exist or does not relate to the safety of the product, or is directly attributable to user abuse or lack of maintenance, you may submit such evidence in accordance with 21 CFR 1003.30 within 30 working days of the receipt of this letter.

Report the results of your investigation and follow-up actions to this office within 15 working days of the receipt of this letter. Your response should include (a) the date the corrective action was completed and copies of service records and other supportive documentation, and (b) an explanation of specific steps your company has initiated to prevent the recurrence of similar violations.

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Steven J. Miller
May 29, 1998

If corrective actions cannot be completed within 15 working days of the receipt of this letter, 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).

Please note that improper installation (including failure to follow installation instructions) which causes the system to be non-compliant with the Performance Standard may cause the system to be adulterated under Section 501(c) of the Act in that the system would not be of a quality represented by its labeling (including its certification label).

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

Your response should be sent to:

Thomas W. Garvin
Food and Drug Administration
2675 N. Mayfair Road, Suite 200
Milwaukee, WI 53226-1305

Any questions regarding the field test may be directed to Mr. Garvin at (414) 771-7167 ext. 12.

Sincerely,


James A. Rahto
Director
Minneapolis District