



DEPARTMENT OF HEALTH & HUMAN SERVICES

HFZ-35 3/1/98
D1454B
Public Health Service

Food & Drug Administration
1141 Central Parkway
Cincinnati, OH 45202

• March 2, 1998

WARNING LETTER

CIN-WL-98-201

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Ted Nemetz
Great Lake Zone Service Manager
Picker International, Inc.
600 Beta Drive
Mayfield, Ohio 44143

REFERENCED TEST NO.: GI-64194

Dear Mr. Nemetz:

On February 25, 1998, the State of Ohio, under contract with Food & Drug Administration, performed a field test of a certified diagnostic x-ray system that your firm reassembled on June 19, 1997. We received notice of the assembly on Form FDA 2579, Assembler Report No. D218252 (Report of Assembly of a Diagnostic X-Ray System). 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 # AR/UF64194 was performed at:

[REDACTED]

System identification:

X-Ray Control Manufacturer: General Electric
X-Ray Control Model No.: 46-276420G1
X-Ray Control Serial No.: 458176WK5
Date of Manufacture: 2/95
Room Number: #1

Our analysis of the field test data indicates that the system does not comply with the following item of the performance standard:

Primary Protective Barrier - 21 CFR 1020.32 (a) (1)

For the undertable fluoroscopic system, x-ray production is possible when the primary protective barrier is not in position to intercept the primary x-ray beam.

The performance standard requires that the x-ray tube used for fluoroscopy shall not produce x-rays unless the barrier is in position to intercept the entire useful beam.

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

1. If you determine that the deviation and/or defect is caused by improper assembly or installation, **you must correct the noncompliance item at no charge to the user by either repairing the system, replacing it or refunding the cost.**
2. If you determine that the deviation is caused by the factory-based manufacturer, you must notify him of the noncompliance item 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 15 working days of receipt of this letter.

You must report the results of your investigation and follow-up to this office within 15 working days of receipt of this letter. Your response should include the date the corrective actions were completed and copies of service records and/or other supportive documents. If you do not respond within 15 working days, the FDA may consider you to be in violation of the Federal Food, Drug and Cosmetic Act (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).

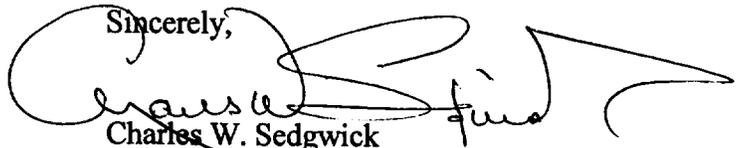
Please note that improper installation, including failure to follow installation instructions that cause the system to be noncompliant with the Performance Standard may cause the system to be adulterated. Under 501© of the Act the system would not be of a quality represented by the labeling (including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

Failure to promptly correct this violation 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 the 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 \$1000 per violation and up to a maximum of \$300,000.

You should 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 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. Your response should be sent to R. Terry Bolen, Radiological Health Compliance Officer and Auditor, Food and Drug Administration, 1141 Central Parkway, Cincinnati, Ohio 45202.

If you have any questions, R. Terry Bolen can be contacted at (513) 684-3501, extension 138.

Sincerely,



Charles W. Sedgwick
Director, Compliance Branch
Cincinnati District

c.

[REDACTED]

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