



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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APR 8 1999

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

WARNING LETTER

VIA FEDERAL EXPRESS

Mr. Howard C. Thomas  
President/Owner  
Applied X-Ray Technologies, Inc.  
2727 West 92<sup>nd</sup> Avenue, Suite 10  
Denver, Colorado 80221

Dear Mr. Thomas:

In reviewing our files, we have discovered that we have not closed out the findings of an inspection of your firm located in Denver, Colorado, on February 24 through March 5, 1998. We apologize for this delay. During this inspection, investigators from the Food and Drug Administration (FDA) determined that your firm has made and sold the AXT 150 U/T Automatic Collimator for export with the Multi-Format AXT 1400 Spotfilm Device. 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 your firm has been manufacturing and selling the Multi-Format AXT 1400 Spotfilm Device both domestically and internationally. As of this date, you still have not provided FDA with a product report as required by 21 CFR 1002.10 or annual reports as required by 21 CFR 1002.13. Under Section 538(a)(1) and (5)(B) of Subchapter C - Electronic Product Radiation Control (EPRC) (formerly the Radiation Control for Health and Safety Act of 1968) of the Act, it is unlawful for any manufacturer to introduce or to deliver for introduction into commerce any electronic product which does not comply with an applicable standard. In addition, it is unlawful for a manufacturer to issue a certification when such certification is not based upon a test or testing program meeting the requirements of section 534(h). Such testing or quality control program must be provided in a product report to FDA prior to introduction into commerce. Any of these products which your firm has introduced into commerce and labeled as certified to 21 CFR Subchapter J may be considered misbranded because there are no product reports or annual reports received by FDA identifying the testing and quality control programs for certification. You must provide us your product reports and annual reports within 45 days from the receipt of this letter.

The above-stated inspection revealed that your firm obtained a section 510(k) clearance (#K882492) on July 21, 1988, to manufacture the Single-Format EXT 950 Spotfilm Device, but then sold the rights to manufacture to Eureka X-Ray Tube, Inc.,

Arlington Heights, Illinois, in [redacted]. Eureka manufactured and distributed from [redacted] units. In [redacted], your firm bought back the rights to the device, but you state you never manufactured the Single-Format EXT 950 Spotfilm Device. You claim your firm only provides service and support for those manufactured and distributed by Eureka. Please describe in detail the service and support that your firm has provided for these devices so that we can determine whether a product report is required by your firm. The fact that you bought the rights to the device, does not mean you have provided FDA with the product report. Even if you have a copy of their product report you must still file a product report under your letter head with your firm's test and quality control procedures for certifying the device. The ownership of a report does not automatically imply your production is following that report step for step with the same quality control.

The above-stated inspection also revealed that your firm currently has [redacted] AXT 150M Manual Collimators being beta tested by [redacted] x-ray system manufacturers ([redacted] domestic and [redacted] international). You did indicate during the inspection that you are in the process of preparing a product report for this device. You must submit this product report prior to introduction into commerce. Please clarify the current status of the AXT 150 U/T Automatic Collimator. Has the product been sold domestically? Do any of the domestic/internationally marketed U/T collimators bear a certification label? If either question is answered in the affirmative, the U/T collimator is in violation of Subchapter C EPRC of the Act and may be in violation of Sections 501 and 502 of Subchapter A- Drugs and Devices of the Act. You must provide a product report for the U/T collimators prior to introduction into commerce. In addition under the EPRC Act, you are obligated to notify FDA when you discover any noncompliance with your products. If there are any other certifiable diagnostic x-ray components that you manufacture which have not been included in this report which are in violation of the Act, please include those models in your response letter.

Since you have already introduced into commerce noncompliant Multi-Format AXT 1400 Spotfilm Devices, you must respond in writing within 15 days of receipt of this letter to one of the options listed below:

1. Refutation - You may submit your views and evidence in accordance with 21 CFR 1003.11 to establish that the alleged noncompliances do not exist, do not relate to the safety of the product, or are directly attributable to user abuse or lack of maintenance.

2. Exemption Request - You may request an exemption from user and dealer/distributor notification and from obligation to correct the violative products. You must include the grounds upon which such exemption is requested (see 21 CFR 1003.30 and 1003.31). Also indicate all models and brands that are to be covered by the exemption along with the number produced and dates of production.
  
3. Purchaser Notification and Corrective Action - If you neither refute the noncompliance nor request an exemption, then you must: (a) notify purchasers and dealers/distributors of the violative products as specified in 21 CFR 1003.10(b), and (b) submit a written corrective action plan (CAP) to fulfill your obligation under 21 CFR 1004.1 to repair, replace, or refund the cost of the violative products at no charge to the user.
  - a. Notification Letter - Requirements for preparation of notification letters are prescribed in 21 CFR 1003.21 and 1003.22. A copy of the notification letter(s) sent to purchasers and dealers must also be sent to this office. It is recommended that you submit a draft of any letters to us for review and concurrence prior to mailing.
  
  - b. Corrective Action Plan - Instructions for preparation of a CAP may be found in 21 CFR 1004.2, 1004.3, and 1004.4. In accordance with 21 CFR 1003.11(b), you must also notify us of the total number and location of units produced (including identification of all models and brands involved) and the approximate number that have left the place of manufacture. In addition, if the product distribution was confined to specific geographical areas of the United States, please specify those areas.

Failure to respond to this letter or to correct these products in a timely manner can result in regulatory action being initiated by the FDA without further notice. These actions may include an injunction and/or imposition of civil penalties as provided for in section 539 of the Act. Persons failing to correct violations are subject to civil penalties of up to \$1,000 per violation and up to a maximum of \$300,000.

If you request additional time to investigate the extent of the problem or to prepare your refutation, notification, CAP, or evidence to support a requested exemption, you must provide the

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reasons for any delays and a reasonable target date for the full submission of your response. Be aware that if an acceptable CAP cannot be prepared promptly, you may be required by 21 CFR 1003.11(c) and 1003.21 to proceed with interim notification to affected persons. Therefore, you are encouraged to immediately begin your preparation of accurate user location lists.

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. 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.

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 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 the attention of Ms. Xuan T. Vo of the Diagnostic Devices Branch, Division of Enforcement I at the above letterhead address, with a copy to the Denver District Office, Food and Drug Administration, Building 20 - Denver Federal Center, P.O. Box 25087, Denver, Colorado 80225.

Sincerely yours,

*Lillian J. Gill*  
for  
Lillian J. Gill  
Director  
Office of Compliance  
Center for Devices and  
Radiological Health