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WARNING LETTER

VIA FEDERAL EXPRESS

Ref:OC:I1-1742

Mr. Kenneth D. Buroker
Director, Regulatory Affairs
Lunar Corporation
313 West Beltline Highway
Madison, Wisconsin 53713

Dear Mr. Buroker:

We have reviewed your product report supplement of October 18, 1996, (listed at the end of this letter), which responded to our letter of July 12, 1996, pertaining to the EXPERT x-ray bone densitometer. We would like to advise you of the following:

- 102.4 1. The duplicate label for the tube housing assembly (THA) that you supplied (#17227, revision B, Attachment A) did not include a manufacture date. It is, therefore, noncompliant with the labeling requirements of 21 CFR 1010.3. In addition, the label changes we required in our July 12, 1996, letter are also required to comply with the labeling requirements. You also have listed the same model number for the THA as for the tube insert (i.e., 11148 in Attachment D). You have not properly identified the model of the THA with your duplicate labeling, and, thus, your labeling is noncompliant.
2. Regarding the "Expert Label Verification" work instruction (#EXQC0053, rev. H, 10/14/96, Attachment E):
- a. Items 3 (page 3) and 7 (page 4) noted "If this is for a replacement part, this label should not be attached to the detector shroud, but is to be taped to the HV power supply." and "If this is for a replacement part, this label should not be attached to the tube head shroud, but is to be included with the tube head assembly.", respectively. These do not appear to be correct. If you do not replace the duplicate label on the shroud, then you will have the wrong serial number listed for viewing and the two labels will not agree. You must assure that the labels on the certified component under the shroud have the identical information as the ones on the shroud which can be seen. Additionally, it is not clear

- b. Since item 1 (page 3) has already verified that the Varian tube head labels are affixed to the THA, item 7 (page 4) is to be revised to verify that a duplicate label is affixed to the tube head shroud instead of the tube head. Additionally, is 11148/B100T or B100T a model number of the tube housing? Does your firm designate a model number of 11148 to the THA? Does the housing model number of the labels affixed to the THA match that of the duplicate label affixed to the tube head shroud? Please clarify these and modify this work instruction as necessary.

102.6 3. Regarding the service manual (#17177, rev. D, November 1995, Attachment G):

- a. Pages 4 and 11 of Appendix 8.S (also Attachment F) did not include instructions for affixing an appropriate duplicate label on the tube head shroud or detector shroud, which matches the appropriate component label, when the tube head shroud or detector shroud is replaced, respectively.
- b. The "Expert Alignment" work instruction (#EXMA0029, rev. C, 08/17/95, Appendix 8.E) and its associated data sheet (#EXMA0030, 08/17/95, Appendix 8.F) verified the center of the x-ray field aligns with the center of the image receptor to within 2 percent of the SID (steps 14 and 17) but did not verify the x-ray field at the plane of the image receptor does not exceed each dimension (top, bottom, left, and right) of the image receptor by more than 2 percent of the SID when the axis of the x-ray beam is perpendicular to the plane of the image receptor as required by 21 CFR 1020.31(f)(4). Additionally, the rejection limit set forth in the above work instruction pertaining to alignment of the center of the x-ray field with the center of the image receptor (i.e., $> \pm 1\text{mm}$) is inconsistent with that (i.e., $> 21.6\text{mm}$) set forth in step 22 of the "Expert Alignment and Beam Size Verification" work instruction (EXQC0009, rev. B, 05/11/95, Appendix 8.G).

102.7 4. The accuracy specification for mA (i.e., $\pm 1\%$) stated on page 1.9 of the operator's manual (version D, September 1996, Attachment H) is inconsistent with that (i.e., $\pm 2\%$) noted on pages 3-4 of Appendix 8.B of

the service manual, pages 2 and 13 (item 52) of the production test procedure EXQC0015 (05/19/94, Supplement 02), and page 2 of its associated data sheet EXQC0016 (05/19/94, Supplement 02).

- 310.5 5. The production test procedure for mA (#EXQC0015) did not perform testing at the low and medium mA values (i.e., approximately 1mA and 3mA) to assure that the maximum deviation of all the tube currents shall not exceed the accuracy limit provided to the user.
- 324.5 6. The "Expert Alignment and Beam Size Verification" work instruction (#EXQC0009, rev. B, 05/11/95, Appendix 8.G) and its associated data sheet (#EXQC0010, 05/11/95, Appendix 8.H) verified the center of the x-ray field aligns with the center of the image receptor to within 2 percent of the SID and verified the size of the x-ray field (step 22) but did not verify the x-ray field at the plane of the image receptor does not exceed each dimension (top, bottom, left, and right) of the image receptor by more than 2 percent of the SID when the axis of the x-ray beam is perpendicular to the plane of the image receptor as required by 21 CFR 1020.31(f)(4). Please be advised that this requested verification must be included in the work instruction EXQC0009 or the work instruction EXMA0029 (see the item 3b above).

Because you have already introduced a product which fails to comply with an applicable standard, you are required to provide notification under 21 CFR 1003.21 to all affected persons and under 21 CFR 1004 to provide a plan for corrective action for a recall of your product.

You must respond in writing within 15 working days of receipt of this letter to one of the options listed below. 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.

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.

Failure to respond to this letter or to correct these products in a timely manner can result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions may include an injunction and/or imposition of civil penalties as provided for in section 539 of the Federal Food, Drug, and Cosmetic 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 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.

When you have completed any production changes necessary to assure compliance of future units and you have submitted the required product report supplements, you may resume introduction of these products into commerce.

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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 Minneapolis District Office, Food and Drug Administration, 240 Hennepin Avenue, Minneapolis, Minnesota 55401-1999. Please reference accession #9311972 for answers to your product report supplement questions for production and reference I1-1742 for response to CAP for noncompliant products already introduced into commerce. Should you have any questions regarding this letter, please contact her at this address, telephone (301) 594-4591, or fax (301) 594-4636.

Sincerely yours,

for Adrienne Galdi

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

Type of Report

Accession Number

Date Received

Supplement 12

9311972-12

October 22, 1996