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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 9 1997

WARNING LETTER

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

Ref:OC:I1-1755

Mr. Terry W. Schwalenberg
Director, Regulatory Affairs
Norland Corporation
W6340 Hackbarth Road
Fort Atkinson, Wisconsin 53538-8999

Dear Mr. Schwalenberg:

This letter is to advise you of items of noncompliance with the Federal performance standard for diagnostic x-ray systems and their major components encountered during our review of your product report, dated September 18, 1995, on the pDEXA™ x-ray bone mineral densitometer manufactured by your firm as follows:

- A. The labels (supplied in appendix A) for the 476D008 tube housing assembly (THA), 476D014 high-voltage (HV) generator, and 476A027 x-ray control did not show a manufacture date, and the label for the 476D008 THA did not show the address of the manufacturer and/or the place of manufacture as required by 21 CFR 1010.3.
- B. One of the x-ray field dimensions at the plane of the image receptor exceeds (i.e., cm) the corresponding edge of the image receptor by more than 2% of the source-image receptor distance of 16 cm (i.e., 0.32 cm) as specified in 21 CFR 1020.31(f)(4).

Because your firm has already introduced a product which fails to comply with an applicable standard, your firm is required to provide notification under 21 CFR 1003.21 to all affected persons and under 21 CFR 1004 to provide a corrective action plan (CAP) 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. 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 reports or supplements, you may resume introduction of these products into commerce.

In addition to the above-stated items of noncompliance, the following information, documents, modifications, and clarifications are needed before our evaluation can be completed. Our comments and questions are keyed to "A Guide for the Submission of Initial Reports on Diagnostic X-Ray Systems and Their Major Components," dated January 1982.

102.1, 1. You should list in these sections the model
102.2, designations of 476D014, 476A027, and 476D008 for
and the HV generator, x-ray control, and THA,
102.5 respectively, not

Also, for those components that are being certified by Lunar, you should list Lunar as manufacturer in section 102.5 and on page 2 of the "pDEXA On-Site Installation Procedure" (P/N 476S006, rev. A, appendix B), not

It is the certifying manufacturer of the components as specified in 1020.30(a)(1)(i) that must comply with the regulations and submit the required information in this report. You must identify the model names of certifiable components in your system which are certified by you. Diagnostic x-ray components that are certified by other manufacturers or reported in other product (initial) reports should be listed in section 102.5.

102.4 2. Please confirm whether there exist labels for the 476D014 HV generator and 476D008 THA which are directly affixed to these respective components as well as are accessible to view (without using tools) as required by 21 CFR 1010.3(a). If these required

labels are inaccessible to view, then explain how duplicate labels for these components are used, and where in the assembler's manual instructions to ensure matching of labels when replacing components and/or panels covering these components can be found.

3. Please explain why the label for the bone densitometer system and item 8.1 of the "pDEXA Final Assembly & Test Procedure" (P/N 476S004, Rev. A, dated 09/14/95, appendix B) showed a model of 476A004 instead of a model of pDEXA as noted in section 102.5. Note: The Federal performance standard does not require a system label, but requires individual component labeling and identification.

102.6 Regarding the "pDEXA On-Site Installation Procedure":

4. Page 2 noted an x-ray control model of 476A003 manufactured by . You have not provided the information on this model as specified in 102.1, 102.4, 102.5, 203, 307, 309-310, and 312. Please advise us of who certifies this model and whether a product report has been filed for it. Be aware that the labeling requirements are requirements on the certifying manufacturer, not necessarily the fabricator of the component.
5. It did not provide all the information as specified in 21 CFR 1020.30(g)(1)-(3).

102.7 Regarding the operator's manual (P/N 476D001, version A, 08/08/94, appendix C):

6. It must contain kVp, mA, and exposure time accuracy statements as required by 21 CFR 1020.30(h)(3)(vi) since the kVp, mA, and exposure time are displayed on the monitor screen prior to the scan (page 5-6, Figure 5.3). The accuracy of the pre-indicated technique factors is a responsibility of the certifying manufacturer.
7. It did not provide all the information as specified in 21 CFR 1020.30(h)(2)(i)-(iii), (3)(i)-(iii), (3)(v), and (3)(viii).

8. Please explain why the table on page vii showed the x-ray dose for the high precision measurement scan is 3.20 mR while item 6.15 (pages 11 and 18) of the "pDEXA Final Assembly & Test Procedure" noted the dose should be less than .
9. Page vi noted a x-ray source of less than 0.1 mA which is inconsistent with that (anode current of 0.1 mA) set forth on page 5-6 of the operator's manual and on page 12 of the "pDEXA Final Assembly & Test Procedure."
- 201.1 and 202.10 10. You noted the maximum tube potential of 65 kVp which is inconsistent with that (60 kVp) set forth on pages vi and 5-6 of the operator's manual and on page 12 of the "pDEXA Final Assembly & Test Procedure."
- 202.7 11. Provide the information as specified in this section.
- 203.4a 12. Provide the operating ranges and accuracy limits for the kVp, mA, and exposure times. Is the system operated at the constant kVp and mA values (i.e., 60 kVp [or 65 kVp?] and 0.1 mA)?
- 302 13. Item 6.7 of the data sheet associated with the "pDEXA Final Assembly & Test Procedure" did not show a measurement unit for the beam quality acceptance criterion (i.e., >0.5).
- 309 and 310 14. The stability test in items 5.7 and 6.6 of the "pDEXA On-Site Installation and Procedure," and of the "pDEXA Final Assembly & Test Procedure," respectively did not include accuracy limits for the peak tube potential and tube current. Please identify or provide the stability test results.
- 312 15. You noted "the pre-indication screen includes an estimate of the time required to complete the scan." Please be advised that this section is applicable to the system and 21 CFR 1020.31(a)(4) requires the exposure time testing procedure include an accuracy limit.

- 319 16. On May 6, when asked by one of our staff, Xuan T. Vo, you told her that the pDEXA system no longer has a fixed source-image receptor distance (SID) of cm, but a fixed SID of cm instead. Please advise us of when this SID change took place and the supplement number used to notify FDA. For this change, your firm may need to designate a new model for the THA, which includes a beam limiting device (BLD), and for the system (if desired) and must ensure that the BLD with a SID of cm must be compatible and that the combination will still meet all applicable requirements through the testing and quality control program for certification; therefore, your firm is required by 21 CFR 1002.10 to file a product report.
17. Please provide a testing procedure for the x-ray field size determination and center alignment as required by 21 CFR 1020.31(f)(4). Also, provide the x-ray field center alignment test results.
18. Regarding the x-ray field size test results supplied in appendix 319, please clarify the following concerns:
- a. Why are the two detectors used instead of one?
 - b. Why are the two detectors separated from each other?
 - c. Why is the x-ray field size at the image receptor plane designed to have a small width and large length as compared with those of the image receptor size?
 - d. Why is the pDEXA system designed with such a low field size detector efficiency of approximately ? The x-ray field size limits in the performance standard were established for conventional x-ray equipment tolerances with x-ray field size area efficiencies of about 84%.

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.

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Please reference accession number 9512022 for response to product report questions/comments and reference I1-1755 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 Gald

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

Type of Report

Accession Number

Date Received

Product Report

9512022-00

October 16, 1995