K992125

NOV 22 1999

510k Summary

as required by 807.92(c) for

XR 46 DXA Bone Densitometer

Prepared June 1999

Submitted by: Norland Medical Systems, Inc.
W6340 Hackbarth Road
Fort Atkinson, WI 53538
Reg. # 2124648

Contact Person:
Mr. Terry Schwalenberg
Director Regulatory Affairs
920-563-8456 x229

Device Trade Name: Model **XR 46** DXA Bone Densitometer

Common Name: DXA table (central) bone densitometer

Classification: Bone densitometer, (21 CFR 892.1170), product code 90KGI; Class II

Predicate Devices: XR 26 DXA bone densitometer (K881865),
Body Composition Assessment (K973459),
Reference Population (K964307), and
Fracture Risk Assessment for Norland bone densitometers (K980569).

Description of Device: The XR 46 is a full featured, pencil beam, DXA, table bone densitometer that scans the Hip, Spine, Forearm, Whole Body, and other user selectable sites. It provides values for BMD, BMC, and Area. It trends follow-up scan values to provide long and short term % change. It also provides side-by-side comparison images and angulated cursors.

The XR 46 compares patient values to gender and ethnic matched reference populations and provides T-Score, Z-Score, % Young Reference, and % Age Matched values.

The XR 46 includes Fracture Risk assessment based on the World Health Organization (WHO) criteria. In general, this means that patients with T-Scores above -1 are considered to be normal; with T-Scores from -1 to -2.5 are considered to be osteopenic and have an increased risk of fracture; and T-Scores below -2.5 are considered to be osteoporotic and have a high risk of fracture.

The XR 46 includes Body Composition assessment and provides lean, fat, and % fat values. It also provides hydrostatic weighing values based on the Siri and Brozek equations.

The XR 46 includes a Report Writer that allows the operator to customize the appearance of their reports and to automate the tedious part of the report. It also allows the user to enter ranges of patient values and the specific statements they want to be printed on their reports for each of these ranges.

Safety and Effectiveness: The XR 46 is comparable to other DXA bone densitometers currently in the market. It does not raise any new safety or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 22 1999

Terry Schwalenberg
Director Regulatory Affairs
Norland Medical Systems, Inc.
W6340 Hackbarth Road
Fort Atkinson, WI 53538

Re: K992125
Model XR 46 DXA Bone Densitometer
Dated: November 5, 1999
Received: November 5, 1999
Regulatory class: II
21 CFR 892.1170/Procode: 90 KGI

Dear Mr. Schwalenberg:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Capt. Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

E

INDICATIONS FOR USE STATEMENT

510(K) Number (if known): K992125

Device Name: **XR 46** DXA Bone Densitometer

Indications For Use:

The XR 46 performs DXA scans of the AP Spine, Hip, Forearm, Lateral Spine, and Whole Body, as well as other user selectable sites. It provides BMD (g/cm2), Area (cm2), and BMC (g) values. It compares these values to gender and ethnic matched reference populations and provides T-Score and % Young Reference, Z-Score and % age matched, and long term and short term change values. This includes sBMD (mg/cm2).

The XR 46 performs soft tissue assessment and provides lean mass, fat mass, percent fat, and total soft tissue values for all scan sites, including Whole Body.

The XR 46 includes a Report Writer that allows the operator to customize the appearance of their reports and to automate the tedious part of the report. It also allows the user to enter ranges of patient values and the specific statements they want to be printed on their reports for each of these ranges.

The bone density measurements from the XR 46 can be used as an aid to physicians in determining fracture risk.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K992125

Prescription Use ✓ OR Over-The-Counter-Use ____
(Per 21 CFR 810.109)