

K99 3176

JUN 20 2000

510k Summary

as required by 807.92(c) for

Multi-Racial Reference Population For pDEXA™ and Discovery™ Bone Densitometers

Prepared September 1999

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

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

Device Trade Name: Multi-Racial Reference Population for pDEXA™ and Discovery™

Common Name: Reference Population for DXA bone densitometer

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

Predicate Devices: Norland pDEXA with Reference Population (K931996), and Norland Fracture Risk Assessment (K980569)

Description of Device: In general, the Multi-Racial Reference Population capability for the pDEXA and Discovery bone densitometers compares the pDEXA and Discovery scan results to average values for people without bone related disease, who have the same gender and ethnic background as the patient. Its purpose is to aid the physician in determining the presence of bone disease other than age related bone loss. Both age matched and young reference comparisons are made. T-Score, Z-Score, % Young Reference, % Age Matched, and a graphical representation are presented.

The Norland pDEXA and Discovery bone densitometers scan the forearm using the industry standard DXA pencil beam technology to assess bone density of the distal and proximal radius plus ulna sites. The Discovery is a newer, smaller version of the pDEXA with faster scan speeds and lower dose. The Discovery dose is < 1 mRem and the pDEXA is < 3 mRem. Discovery scan time is about 90 seconds and the pDEXA about 3 minutes.

This reference population also includes Fracture Risk Assessment based on the World Health Organization (WHO) criteria. In general, this means that patients with T- Scores between -1 to -1 are considered to have a low risk of fracture; with T-Scores from -1 to -2.5 are considered to have a medium risk of fracture; and T-Scores below -2.5 are considered to have a high risk of fracture.

Safety and Effectiveness: This pDEXA and Discovery multi-racial reference population is comparable to reference population capabilities in use with other bone densitometers in the industry. No new safety or effectiveness issues are raised with this capability.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 20 2000

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

Re: K993176
Multi-Racial Reference Population for the
pDEXA™ and Discovery™ Bone Densitometers
Dated: May 16, 2000
Received: May 22, 2000
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 (Pre-market 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) 594-4591. 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" (21CFR 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,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

INDICATIONS FOR USE STATEMENT

510(K) Number (if known): K993176

Device Name: **Multi-Racial Reference Population for the
pDEXA™ and Discovery™ Bone Densitometers**

Indications For Use:

The bone density estimates from the pDEXA™ and Discovery™ Bone Densitometers can be compared to gender and ethnic matched reference populations as an aid in determining the presence of bone disease other than age-related bone loss. T-Score, % Young Reference, Z-Score, % Age Matched, and long and short term change values are provided. These reference populations include Caucasian, Afro-American, Hispanic, and Asian men and women.

The bone density estimates from the pDEXA™ and Discovery™ bone densitometers 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)

Prescription Use OR Over-The-Counter-Use

Elaine Perle (Division Sign-Off)
Per 21 CFR 810.109

Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K993176