K980569

JUN 12 1998

510k Summary

as required by 807.92(c) for

Fracture Risk Assessment Capability

for Norland X-Ray Bone Densitometers

Prepared February 1998

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:	Fracture Risk Assessment Capability for Norland X-Ray Bone Densitometers
Common Name:	Fracture risk assessment for bone densitometers
Classification:	Bone densitometer, (21 CFR 892.1170), product code 90KGI; Class II
Predicate Devices:	Fracture Risk Assessment for pDEXA™ Bone Densitometer (K973104) Norland Medical Systems, Inc., Fort Atkinson, WI Fracture Risk Assessment for the Norland-Cameron Model 178 Bone Mineral Analyzer; which is a pre-amendment device.
Description of Device:	This fracture risk assessment capability provides information that aids the physician in determining risk of fracture, risk of bone disease, or treatment effectiveness. This fracture risk assessment capability interprets the results of the bone density tests performed by Norland bone densitometers in accordance with methods in general use in the medical community. In general they use the bone densitometer values (usually BMD and T-Score) and patient information (usually gender, age, and ethnic background). The interpretation is based on the World Health Organization's (WHO) criteria relating bone density to risk of fracture and diagnosis of osteoporosis. In general, the WHO criteria means that patients with T-Scores from +1 to -1 are considered to be normal; with T-Scores from -1 to -2.5 are considered to have low bone mass and have an increased risk of fracture; and with T-Scores below -2.5 are considered to be osteoporotic

and have a high risk of fracture. This information is presented graphically and as verbiage on the screens and reports.

This fracture risk capability does not require any modifications to the Norland bone densitometers besides adding the fracture risk information to the screens and printouts. In particular, it does not increase the scanning time, patient dose, or scatter radiation.

Safety and Effectiveness:

This Norland Fracture Risk Assessment Capability is comparable to fracture risk assessment capabilities in use with other bone densitometers in the industry. No new safety or effectiveness issues are raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUN 12 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K980569
Fracture risk capabililty for the Norland Bone Densitometer: Models XR Series, pDEXA Series, Apollo Series, XCT Series and SXA Series
Dated: April 16, 1998
Received: April 20, 1998
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 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,

Lillian Yin, Ph.D.
Director, Division of Reproductive, Abdominal, Ear, Nose and Throat and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(K) Number (if known):_____

Device Name: **Fracture Risk Assessment Capability** for Norland X-Ray Bone Densitometers.

Indications For Use:

The bone density estimates from Norland X-Ray Bone Densitometers can be used as an aid to the physician in determining risk of fracture.

(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____
(Per 21 CFR 810.109)

David A. Bergman
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K980569