

K973104

JAN 29 1998

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
as required by 807.92(c) for

APPENDIX D

Supplement 9/97

FRACTURE RISK ASSESSMENT OPTION

for the Norland pDEXA™ Bone Densitometer
Prepared 29 September 1997

SUBMITTED BY: Norland Corporation
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Director Regulatory Affairs
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TRADE NAME: Fracture Risk Assessment Option for the Norland Model pDEXA™ Bone Densitometer (Fracture Risk Option)

CLASSIFICATION: Densitometer, Bone (90KGI) (21 CFR 892.1170), Class II
COMMON NAME: fracture risk assessment for dual energy bone densitometer

PREDICATE DEVICE: Fracture Risk Assessment for the Norland-Cameron Model 178 Bone Mineral Analyzer (Model 178); which is a pre-amendment device.

DEVICE DESCRIPTION: The Fracture Risk Option consists of updated software which adds the fracture risk features to the screens and printed reports for the pDEXA. It also includes a supplement to the pDEXA Operator's Guide which explains how to interpret the pDEXA bone density values to aid in the assessment of fracture risk and the diagnosis of osteoporosis.

INTENDED USE: The Fracture Risk Option provides an assessment of relative fracture risk based on the T-Score value. It presents the World Health Organization's (WHO) definition of osteoporosis and osteopenia; and makes the same diagnostic recommendations originally made by the pre-amendment Model 178. It also indicates that although bone density is the single most important factor in the assessment of fracture risk and the diagnosis of osteoporosis, other factors must also be considered by the physician in their diagnosis. Some of these factors are provided and others are referenced.

SUBSTANTIAL EQUIVALENCE: The Fracture Risk Option is substantially equivalent to the pre-amendment fracture risk assessment capability of the Model 178, because they both have the same intended use. They both assess the subject's bone density, then compare it to a reference population (device specific), and then assess fracture risk based on the number of standard deviations below the mean of the reference population. Further, they both claim increasing fracture risk for larger deviations below the mean and provide recommendations to the physician regarding diagnosis and treatment.

STATEMENT OF SUBSTANTIAL EQUIVALENCE

The Fracture Risk Assessment Option for the Norland pDEXA Bone Densitometer (Fracture Risk Option) is substantially equivalent to the pre-amendment fracture risk claims of the Norland-Cameron Bone Mineral Analyzer (Model 178) because they both have the same intended use based on the following:

- Both assess bone density of the forearm.
- Both compare this bone density assessment to a reference population in terms of the number of standard deviations the value is below the mean. In both cases this reference population is device specific.
- Both assign increasing risk of fracture for larger deviations below the mean.
- Both make the same recommendations to physicians relating to diagnosis and treatment.
- Both state that the physician is responsible for the diagnosis and that the device only provides useful information to aid the physician in his diagnosis.

While there are technological differences between the Fracture Risk Option and the Model 178, they do not impact intended use because it is based on the subject's value relative to a reference population determined for the specific device used. It is the comparison of the subject's value to the reference population in terms of the number of standard deviations from the mean for that reference population, that conveys the intended use. This is the same for the Fracture Risk Option and the Model 178.

The fracture risk claims for the Model 178 are shown in the publication: "Interpretation of Fracture Index Charts; E. Smith and J. R. Cameron"; which was distributed to Norland customers pre-amendment. This publication includes the famous Smith-Cameron charts. See attachment A2.

The main difference between the fracture risk claims of the Fracture Risk Option and the Model 178 is that the Fracture Risk Option determines all three risk regions in terms of young reference values (T-Score), while the Model 178 used age matched criteria (Z-Score) for part of the separation between the two lower risk regions. This difference is not significant because it does not affect the peri-menopausal, post menopausal, or elderly portions of the chart. In these important regions, they both are based on T-Score. Also, even in the younger age region where they are different, the practical implications are minimal.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 29 1998

Terry Schwalenberg
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Re: K973104
Fracture Risk Assessment Option for
the Norland Model pDEXA™ Bone
Dated: November 21, 1997
Regulatory class: II
Received: December 2, 1997
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 requirement, 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/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

ATTACHMENT B

INDICATIONS FOR USE STATEMENT

510(K) Number (if known): K973104

Device Name: Fracture Risk Assessment Option
for the Norland Model pDEXA™ Bone Densitometer

The bone density estimates from the Norland pDEXA™ Bone Densitometer can be used as an aid to the physician 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

(Per 21 CFR 810.109)

David A. Geyman
(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K973104