

Fracture Risk Capability for SXA 3000™ - Supplement 1

February 1998

JUN 12 1998

510k Summary
as required by 807.92(c) for
Fracture Risk Assessment Capability
for the
Norland **SXA 3000™** Bone Densitometer

Prepared February 1998

Submitted by: Norland Corporation
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Director Regulatory Affairs
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Device Trade Name: Fracture Risk Assessment Capability
for the Norland SXA 3000™ Bone Densitometer

Common Name: Fracture Risk Assessment for a single energy x-ray (SXA) bone densitometer

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

Description of Device: The Norland OsteoAnalyzer™ Model SXA 3000™ X-Ray Bone Densitometer (SXA 3000™) can be used whenever it is desirable to do a bone assessment of the os calcis (heel). Bone assessments are of interest in many medical disciplines such as nephrology, endocrinology, rheumatology, gynecology, etc. The SXA 3000™ scans the heel using the industry standard SXA pencil beam technology and provides BMC, Area, BMD, T-Score, and Z-Score values. A scan takes about three minutes and the patient dose is less than 1.5 mRem.

The SXA 3000™ provides fracture risk assessment based on the World Health Organization (WHO) criteria for relating the bone density test to fracture risk assessment and disease diagnosis. In general, this assessment states that patients with T-Scores from +1 to -1 are considered to be

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normal; T-Scores from -1 to -2.5 are considered to have low bone mass and an increased risk of fracture; and T-Scores below -2.5 are considered to be osteoporotic with a high risk of fracture.

Safety and Effectiveness:

This Fracture Risk Assessment Capability for the SXA 3000™ is comparable to fracture risk assessment 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 12 1998

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

Re: K980289
Fracture risk capability for the Norland SXA 3000
Bone Densitometer
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): **K980289**

Device Name: **Fracture Risk Assessment capability
for the Norland SXA 3000™ Bone Densitometer**

Indications For Use:

The bone density estimates from the SXA 3000™ can be used as an aid to physicians in determining fracture risk, based on their comparison to estimates for people without bone related disease, who have the same gender and ethnic background as the patient.

(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. Seaman

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K980289