

MAY 20 1998

K980125

510k Summary
as required by 807.92(c) for
Reference Population Capability
for the Norland Apollo™ Bone Densitometer

Prepared April 1998

Submitted by: Norland Medical Systems
W6340 Hackbarth Road
Fort Atkinson, WI 53538
Reg. # 2124648
920-563-8456

Contact Person: Mr. Terry Schwalenberg
Director Regulatory Affairs

Device Trade Name: Reference Population for young normal Caucasian men and women for the
Norland Apollo™ X-Ray Bone Densitometer

Common Name: Reference Population for dual energy x-ray (DXA) bone densitometer

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

Predicate Devices: Reference Population for pDEXA™ Bone Densitometer (K931996)
Norland Corporation, Fort Atkinson, WI

Fracture Risk Assessment for pDEXA™ Bone Densitometer (K973104)
Norland Medical Systems, Inc., Fort Atkinson, WI

Description of Device: The Norland Apollo™ Bone Densitometer (Apollo™) scans the os calcis (heel) using the industry standard DXA pencil beam technology to assess bone density. A water bath is not required and the scan takes less than 30 seconds. Patient dose is less than 0.5 mRem and scatter radiation is less than 0.1 mRem/hour at 3 feet.

Two reference sets are provided, one for female Caucasians and one for male Caucasians. These reference data sets allow comparison of Apollo™ BMD scan results to healthy young adults aged 20 to 42. The results of the comparison is given in terms of T-Score (the number of standard deviations from the healthy young adult value), % Young Reference (the percentage relative to the healthy young adult value), and in graphical form.

The Apollo™ Reference Population capability also includes Fracture Risk assessment based on the World Health Organization (WHO) criteria. In general, this 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 T-Scores below -2.5 are considered to be osteoporotic and have a high risk of fracture.

Other reference data sets will be available in the future.

Safety and
Effectiveness:

The Reference Population capability for the Apollo™ 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

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

Re: K980125
Norland Apollo™ X-Ray Bone Densitometer
Dated: April 15, 1998
Received: April 17, 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

15 April 98

INDICATIONS FOR USE STATEMENT

510(K) Number (if known): **K980125**

Device Name: **Reference Population** and **Fracture Risk** capability
for the Norland **Apollo**TM Bone Densitometer

Indications For Use:

The bone density estimates from the ApolloTM can be compared to estimates of young normal Caucasian men and women, and as an aid to physicians in diagnosing and managing osteoporosis. The bone density estimates from the ApolloTM 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
(Per 21 CFR 810.109)

David A. Reymon
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K980125