

FEB 13 1998

K973459

510k Summary
as required by 807.92(c) for
Norland Body Composition Option
Prepared January 1998

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

Contact Person: Mr. Terry Schwalenberg
Director Regulatory Affairs

Device Trade Name: Norland Body Composition Option

Common Name: Body Composition Option for DEXA bone densitometers

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

Predicate Devices: Lunar Total Body Software Option for the DPX bone densitometer (K935454)

Description of Device: The Norland Body Composition Option (body composition) is used with Norland DEXA bone densitometers to estimate the relative amounts of lean and fat tissue in the scan area. Body composition does not require any changes to the bone densitometer nor does it require additional scanning or radiation exposure beyond the bone density scans. In most cases, existing scans can be re-analyzed to provide the body composition values. Although body composition is most useful for whole body scans, it is compatible with all scan modes for Norland DEXA bone densitometers.

Body composition values for whole body scans were compared to underwater weighing (UWW) values in clinical studies involving hundreds of subjects. The UWW values were determined using both the Siri and Brozek equations. Based on this study, the Norland body composition provides the Siri and Brozek equivalent values for the Whole Body scans.

Intended use Body composition assesses the non-bone tissue determined during the bone density scans performed by Norland DEXA bone densitometers, and estimates soft tissue mass, fat mass, lean mass, total soft tissue mass, % fat, TBMC/LBM (Total Bone Mineral Content / Lean Body Mass), and Siri and Brozek equation equivalent values.

These body composition estimates are useful to health care professionals in their management of diseases/conditions where the disease/condition itself, or its treatment, can affect the relative amounts of patient fat and lean tissue. The Norland Body Composition Option does not diagnose disease, or recommend treatment regimens, or quantify treatment effectiveness. Only the health care professional can make these judgments. Some of the diseases/conditions for which lean and fat tissue estimates are useful are chronic renal failure, Anorexia Nervosa, excessive obesity, AIDS/HIV, and Cystic Fibrosis. Body composition is also a convenient alternative to hydrostatic weighing and skin fold measurements.

Safety

Body composition doesn't require additional radiation exposure over what is required for the bone density scan alone. The data which is normally analyzed for the bone values can also be analyzed for the lean and fat values. During the scan, the subject lies quietly on a cushioned table (or sits in a chair); they are not required to be in contact with any electrical part or to ingest any chemical/drug.

The delivered dose for Norland bone densitometers range from 0.07 mrem for a whole body scan, to 3 mrem for a pDEXA forearm scan, to 10 mrem for a hip scan. Stray radiation is very small. At a distance of three feet from the x-ray beam, the radiation field is less than 0.1 mRem per hour. This field is present only during the few minutes of the actual patient scan; and is primarily scatter from the patient. Shielded rooms are not required, and the operators are not required to be out of the room during the scan. These dose levels compare favorably to the background radiation level of 100 mrem per year; to a chest x-ray of 35 mrem; and to the increased dose received during a cross country (round trip) airline flight of 5 mrem.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Terry Schwalenberg
Director, Regulatory Affairs
Norland Corporation
W6340 Hackbarth Rd.
Fort Atkinson, WI 53538-8999Re: K973459
Norland Body Composition Option for Norland Dexa Bone Densitometers
Dated: January 5, 1998
Received: January 6, 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 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

Indications for Use

January 1998

510(k) number (if known):

Device Name: **Body Composition Option for Norland DEXA Bone Densitometers**

Indications for use:

The Norland Body Composition Option (body composition) assesses the non-bone tissue determined during the bone density scans performed by Norland DEXA bone densitometers, and estimates soft tissue mass, fat mass, lean mass, total soft tissue mass, % fat, TBMC/LBM (Total Bone Mineral Content / Lean Body Mass), and Siri and Brozek equation equivalent values.

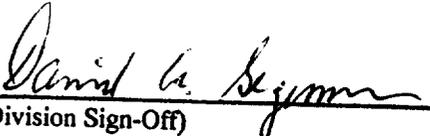
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

OR Over-the-counter Use


(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K973459