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510k Summary
as required by 807.92(c) for
XCT 2000 L pQCT Bone Densitometer
Prepared September 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
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Device Trade Name: Model **XCT 2000 L** pQCT Bone Densitometer
Common Name: Peripheral quantitative computed tomography bone densitometer
Classification: Bone densitometer, (21 CFR 892.1170), product code 90KGI; Class II

Predicate Devices: Norland XCT 960 pQCT bone densitometer (K922286).
Fracture Risk Assessment for Norland bone densitometers (K980569).

Description of Device: The XCT 2000 L performs a Computed Tomography (CT) scan at various user selectable skeletal sites and measures volumetric bone density in mg/cm³. It provides separate values for the inner core of the bone (trabecular region), the outer ring of the bone (cortical region), and the entire bone (Total). It also provides Axial SSI and Polar SSI values as an aid to physicians in evaluating fracture risk and bone strength. These values are calculated from the raw data taken during the CT scan and do not require additional scan time or patient dose.

The XCT 2000 L has a 140 mm measurement diameter, a selectable resolution range of 0.2 to 0.8 mm, a typical scan time of 80 seconds, and a typical dose of 40 mRems. It can do multiple scans at selectable spacing. The XCT 2000 L measures a wide variety of skeletal sites, including the Heel (os calcis), Forearm, Knee, and Tibia.

The XCT 2000 L has an in vivo precision of < 3 mg/cm³ for the trabecular region and < 9 mg/cm³ for the cortical region. It is calibrated to the COMAC phantom with an accuracy of 2 %

The XCT 2000 L also includes Fracture Risk assessment based on the World Health Organization (WHO) criteria. In general, this means that patients with T- Scores above -1 are considered to be normal; with T- Scores from -1 to -2.5 are considered to be osteopenic 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.

Safety and Effectiveness: The XCT 2000 L is comparable to other pQCT bone densitometers currently in the market. It does not raise any new safety or effectiveness issues.



OCT 29 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Terry Schwalenberg
Director Regulatory Affairs
Norland Medical Systems, Inc.
W6340 Hackbarth Rd.
Fort Atkinson, WI 53538Re: K983273
XCT 200 L pQCT Bone Densitometer
Dated: September 16, 1998
Received: September 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

INDICATIONS FOR USE STATEMENT

510(K) Number (if known): K983273

Device Name: **XCT 2000 L** pQCT Bone Densitometer

Indications For Use:

The XCT 2000 L performs a Quantitative Computed Tomography (QCT) scan at various user selectable skeletal sites and measures volumetric bone density (mg/cm³). It provides separate values for the inner core of the bone (trabecular region), the outer ring of the bone (cortical region), and the entire bone (Total). It also provides Axial SSI and Polar SSI values as an aid to physicians in evaluating fracture risk and bone strength.

These bone density estimates can also 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 G. Segerson
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K983273