

K972053

# LUNAR

313 W. BELTLINE HIGHWAY      MADISON, WI 53713      (608) 274-2663

AUG - 8 1997

## 10.0 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 807.92(c).

**Contact Person:** Kenneth D. Buroker  
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313 West Beltline Highway  
Madison, WI 53713

**Phone:** (608) 288-6460  
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**Date:** May 29, 1997

**Device/Trade Name:** PIXI™ young adult reference population for os calcis and forearm.

**Common Name:** Bone Densitometer

**Classification Name:** Bone Densitometer  
21CFR 892.1170

**Predicate Device:** Osteon Osteoanalyzer  
510 (k) K891582

Norland pDEXA  
510 (k) K931996

## 10.1 DESCRIPTION OF DEVICE

The reference BMD values incorporated in this submission, provides the ability to compare the BMD result of the PIXI™, to the value of an average young adult, age 20 - 45 years old, of the same sex. The results from this comparison is expressed as a percentage of young adult, or as a T-score, defined as number of standard deviations from the young adult value.

Data were collected on normal white young adult men and women, age 20 to 45 years. This data is summarized as shown in Table A.

Site	Female			Male		
	n	Mean	SD	n	Mean	SD
Os Calcis	143	0.556	0.089	107	0.682	0.106
Forearm	126	0.523	0.062	91	0.623	0.085

Table A

## 10.2 CONCLUSION

The use of reference values with the PIXI™ bone densitometer is comparable to how reference values are utilized on other commercially available bone densitometers. This feature can be used by the clinician entirely at his/her discretion. No new safety and effectiveness questions are raised with PIXI™ young adult reference population for os calcis and forearm.

  
 \_\_\_\_\_  
*Signature*

Kenneth D. Buroker

*Printed Name*

Director, Regulatory Affairs

*Title*



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

AUG - 8 1997

Kenneth D. Buroker  
Director, Regulatory Affairs  
Lunar Corporation  
313 W. Beltline Highway  
Madison, WI 53713

Re: K972053  
PIXI™ Young Adult Reference Population  
for OS Calcis and Forearm  
Dated: May 29, 1997  
Received: June 2, 1997  
Regulatory Class: II  
21 CFR 892.1170/Procode: 90 KGI

Dear Mr. Buroker:

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

4.0 INDICATION FOR USE FORM

- 501(k) Number (if known) K972053
- Device name: **PIXI™ young adult reference population for os calcis and forearm.**
- Indications For Use:

The PIXI™ young adult reference population for os calcis and forearm provides the ability to compare the BMD result of the PIXI™ to the value of an average young adult, age 20-45 years old, of the same sex. The results from this comparison are expressed as a percentage of young adults, or as a T-score, defined as a number of standard deviations from the young adult value.

This additional feature is highly comparable to similar features in the Norland pDEXA as well as the Osteon Osteoanalyzer densitometers.

The use of the PIXI™ young adult reference population for os calcis and forearm, is restricted to prescription use only. The operator's manual for the PIXI system contains the following statement:

“United States Federal Law restricts this device to the sale, distribution, and use by or on the order of a physician.”

**PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED.**

Concurrence of CDRH, Office of Device Evaluation (ODE)

*[Signature]*  
(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,  
and Radiological Devices

510(k) Number K972053

Prescription Use    
(Per 21 CFR 801.109)

OR

Over-the-Counter Use \_\_\_\_\_   
(Optional Format 1-2-96)