

LUNAR

313 W. BELTLINE HIGHWAY

MADISON, WI 53713

(608) 274-2663

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 LUNAR Corporation 313 West Beltline Highway Madison, WI 53713
Phone:	(608) 288-6460
Fax:	(608) 274-0853
Date:	October 21, 1998
Device/Trade Name:	ORCA-DX Bone Densitometer
Common Name:	Bone Densitometer
Classification Name:	Bone Densitometer 21CFR 892.1170
Predicate Device:	LUNAR PIXI 510(k) k970224

10.1 DESCRIPTION OF THE DEVICE

The ORCA-DX Bone Densitometer provides an estimation of Bone Mineral Density (BMD in g/cm^2) for the heel and forearm, using dual-energy x-ray absorptiometry.

10.2 SUMMARY OF TECHNICAL CHARACTERISTICS

The ORCA-DX[®] Bone Densitometer requires a 4-second exposure, with a total exposure dose of <10 mrem. The radiation exposure of <10 mrem is lower than that for the predicate device and is low compared to the maximum permissible dose for extremities. The BMD estimations correlate ~0.95 with results obtained on the predicate device. The short-term BMD precision (%CV) *in vivo* is <1.5% and is comparable to previously registered devices.

10.3 CONCLUSION

The results from the ORCA-DX Bone Densitometer are comparable to previously registered devices that demonstrate similar precision. No new safety and effectiveness questions are raised with the ORCA-DX Bone Densitometer.



Signature

Kenneth D. Buroker

Printed Name

Director, Regulatory Affairs

Title

10/21/98

Date



DEC 8 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Kenneth D. Buroker
Director, Regulatory Affairs
Lunar Corporation
313 West Beltline Highway
Madison, WI 53713Re: K983724
ORCA-DX Bone Densitometer
Dated: October 21, 1998
Received: October 22, 1998
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 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

3.0 INDICATION FOR USE FORM

- 510(k) Number (if known) _____
- Device Name: ORCA-DX® Bone Densitometer
- Indications for use:

The ORCA-DX® Bone Densitometer provides an estimate of BMD for the heel and forearm.

The ORCA-DX® Bone Densitometer requires a 4-second exposure for BMD with a skin entrance dose of <10 mrem. This instrument is comparable to the Lunar PIXI densitometer. The ORCA-DX® Bone Densitometer poses no new safety or efficacy concerns.

The use of the ORCA-DX® Bone Densitometer is restricted to prescription use only. The operator's manual for the system contains the following statement:

“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)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

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

David A. Beggs
 (Division Sign-Off)
 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices
 510(k) Number K983724