K982267

AUG 25 1998

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:	June 18, 1998
Device/Trade Name:	DPX-RX Bone Densitometer
Common Name:	Bone Densitometer
Classification Name:	Bone Densitometer 21CFR 892.1170
Predicate Device:	LUNAR DPX-Alpha and DPX-L 510(k) Accession Number K904980 LUNAR EXPERT 510(k) K945526

10.1 DESCRIPTION OF THE DEVICE:

The DPX-RX Bone Densitometer provides an estimation of Bone Mineral Density (BMD in g/cm^2) of the lumbar spine and the proximal femur.

10.2 SUMMARY OF TECHNICAL CHARACTERISTICS

The DPX-RX Bone Densitometer performs a 30-second scan, with a total skin exposure dose of 2.5 mrem per measurement. The radiation exposure of 2.5 mrem is comparable to the predicate DPX-L, and is ten times lower than predicate fanbeam densitometers such as the EXPERT.

The BMD estimations in vivo provided by the DPX-RX correlate $r>0.98$ with the DPX-L. The average BMD values obtained in 50 subjects in vivo were very similar with DPX-L and DPX-RX. The average short-term precision (%CV) in vitro was <0.5%. The short-term %CV in vivo was approximately 1.0% for lumbar spine and proximal femur BMD. These values are comparable to those shown on currently marketed devices.

10.3 CONCLUSION

The DPX-RX Bone densitometer is substantially equivalent to currently marketed devices. No new safety and effectiveness questions are raised with the DPX-RX Bone Densitometer.

Signed

Kenneth D. Buroker
Name

Director, Regulatory Affairs
Title

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 25 1998

Kenneth D. Buroker
Lunar Corporation
313 West Beltline Highway
Madison, WI 53713

Re: K982267
Trade Name: DPX-RX Bone Densitometer
Regulatory Class: II
Product Code: 90 KGI
Dated: June 26, 1998
Received: June 29, 1998

Dear Mr. Buroker:

This letter corrects our substantially equivalent letter of August 18, 1998, regarding the name of your device.

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 legally marketed predicate 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 Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General (QS) regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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. 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 at (301) 443-6597 or at its internet address, "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for David A. Segerson

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

- 501(k) Number (if known) _____
- Device name: DPX-RX Bone Densitometer
- Indications For Use:

The DPX-RX Bone Densitometer provides an estimate of BMD at the lumbar Spine and proximal femur regions. This BMD value can then be compared to a reference population at the sole discretion of the physician.

The use of the DPX-RX Bone Densitometer is restricted to prescription use only. The operator's manual for the DPX-RX 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)

David A. Seguin

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K982267

Prescription Use ✓ (Per 21 CRF 801.109) OR Over-the-Counter Use _____ (Optional Format 1-2-96)