FEB 13 1998

K974434

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: November 21, 1997

Device/Trade Name: EXPERT-XL Lateral Spine BMD Acquisition and Analysis Software

Common Name: Bone Densitometer

Classification Name: Bone Densitometer
21CFR 892.1170

Predicate Device: EXPERT-XL Bone Mineral Densitometer, standard AP spine site, 510(k) K945526

10.1 DESCRIPTION OF THE DEVICE:

The EXPERT-XL Lateral Spine BMD Acquisition and Analysis Software is an accessory software option for estimation of Bone Mineral Density (BMD), in g/cm^2, of the lumbar spine vertebrae in the lateral view provided for the EXPERT-XL Bone Densitometer with a reference population for comparative purposes.

10.2 SUMMARY OF TECHNICAL CHARACTERISTICS

The EXPERT-XL Lateral Spine BMD software acquires images of the lumbar spine in the lateral view; the acquisition takes 16 seconds. The results in vitro correlate highly ($r = 0.99$) with BMD on known phantoms, and the precision in vitro is equivalent to the AP spine when

analyzed with a region-of-interest (ROI) of the same dimension. The average short term precision (CV) in vivo is 3.0 to 3.5%; this is higher than that of the AP spine BMD due to smaller ROI's and lower bone density. The female reference population has relatively constant BMD for age 20-49, but BMD decreases after age 50 at a rate of of 0.008g/cm^2 per year (~1% per year). approximately

The radiation exposure (skin entrance) of 120 mrem is higher than that for the AP view but is necessary due to the increased thickness in the lateral view. The exposure remains low compared to the maximum permissible dose.

10.3 CONCLUSION

The EXPERT-XL Lateral Spine BMD Acquisition and Analysis software option is substantially equivalent to the EXPERT-XL standard anterior/posterior (AP) spine projection. The BMD results in vitro show excellent precision and a high correlation to the AP spine. The precision results in vivo are acceptable for the small ROI. The female reference population is relatively constant at the younger age groups with a decline starting after age 50.

No new safety and effectiveness questions are raised with the EXPERT-XL Lateral Spine BMD Acquisition and Analysis software accessory.

Signed

Kenneth D. Buroker
Printed Name

Director, Regulatory Affairs
Title

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 13 1998

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

Re: K974437
Expert-XL Lateral Spine BMD Acquistion and Analysis Software
Dated: November 21, 1997
Received: November 24, 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

3.0 INDICATION FOR USE FORM

- 501(k) Number (if known) _____
- Device name: EXPERT-XL Lateral Spine BMD Acquisition and Analysis Software
- Indications For Use:

The EXPERT-XL Lateral Spine BMD Acquisition and Analysis software is used with the EXPERT-XL bone densitometer system. This software feature estimates bone mineral density (BMD) of the lumbar spine vertebrae in the lateral view. This BMD value can then be compared to a reference population at the sole discretion of the physician.

The EXPERT-XL User's Guide and Technical Manual 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)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K974437

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