NOV 18 1998

LUNAR

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

K983262

9.0 510(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: September 15, 1998

Device/Trade Name: Fracture Risk option for EXPERT-XL Bone Densitometer

Common Name: Bone Densitometer

Classification Name: Bone Densitometer
21CFR 892.1170

Predicate Device: Norland-Cameron Model 178 Bone Mineral Analyzer (pre-amendment)

9.1 DESCRIPTION OF THE DEVICE:

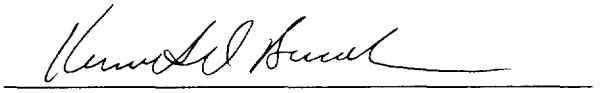
The Fracture Risk option for EXPERT-XL is a new software feature, providing fracture risk assessment based on the patient's bone mineral density T-score.

9.2 SUMMARY OF TECHNICAL CHARACTERISTICS

The Fracture Risk option for EXPERT-XL is a software accessory to aid the physician in assessing fracture risk from the results of an EXPERT-XL bone density examination. The Fracture Risk Assessment Feature does not cause any changes to the scan parameters used in the examination, and it does not affect the results produced.

9.3 CONCLUSION

The Fracture Risk option for EXPERT-XL is substantially equivalent to the Norland-Cameron Model 178 Bone Mineral Analyzer, a pre-amendment device that was used to aid the physician in determining fracture risk. No new safety and effectiveness questions are raised with the Fracture Risk option for the EXPERT-XL 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

NOV 18 1998

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

Re: K983262
Fracture Risk Assessment Option for PIXI Bone Densitometer
Dated: September 15, 1998
Received: September 17, 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) K983262
- Device Name: Fracture Risk option for PIXI Bone Densitometer
- Indications for use:

The Fracture Risk option is used with the LUNAR PIXI bone densitometer system. This option provides an assessment of relative fracture risk based on the patient's T-score value using the categories of fracture risk defined by the World Health Organization (WHO). Physician and patient information is provided to indicate that although bone density is the single most important factor in the assessment of fracture risk and the diagnosis of osteoporosis, the physician should also consider other factors.

The use of the Fracture Risk option for PIXI 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."

The Fracture Risk option for PIXI poses no new safety or efficacy concerns.

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 801.109)

(Optional Format 1-2-96)

David A. Segerson
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K983262