K983564

LUNAR

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

8 1998

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: **Fax:**	(608) 288-6460 (608) 274-0853
Date:	October 9, 1998
Device/Trade Name:	Prodigy Total Body Software
Common Name:	Bone Densitometer
Classification Name:	Bone Densitometer 21CFR 892.1170
Predicate Device:	LUNAR DPX Total Body Software 510(k) K884625/B LUNAR DPX Total Body Tissue Quantitation Software 510(k) K935454

10.1 DESCRIPTION OF THE DEVICE:

The Total Body Software for the Prodigy bone densitometer provides an estimation of Bone Mineral Density (BMD in g/cm^2), lean and fat tissue mass of the total body.

10.2 SUMMARY OF TECHNICAL CHARACTERISTICS

The Prodigy Bone Densitometer performs a 5-minute total body scan, with a total skin exposure dose of 0.13 mrem per measurement.

The BMD estimations *in vivo* provided by the Prodigy correlate r>0.98 with the DPX. The average BMD, and lean and fat tissue mass values obtained in 46 subjects were very similar to the results obtained on a DPX. The average short-term precision (%CV) *in vivo* was <1% for total body BMD, and <1.5% (300g) for lean and fat tissue mass. These values are comparable to those shown on currently marketed devices.

10.3 CONCLUSION

The Prodigy Total Body Software application is substantially equivalent to currently marketed software. No new safety and effectiveness questions are raised with the Prodigy Total Body Software application.

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

DEC 8 1998

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

Re: K983564
Prodigy Total Body Software
Dated: October 9, 1998
Received: October 13, 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

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) K983564
- Device Name: PRODIGY Total Body Software
- Indications for use:

The Total Body Software is used with the Prodigy bone densitometer system. This software provides an estimate of BMD, fat and lean tissue mass. The BMD value can then be compared to a reference population at the sole discretion of the physician.

The Total Body Software requires a 5-minute exposure, with a total effective dose of 0.13 mrem. This software is substantially equivalent to the DPX Total Body software and poses no new safety or efficacy concerns.

The use of the Prodigy Bone Densitometer is restricted to prescription use only. The operator's manual for the Prodigy 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 G. Hoyme

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K983564

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)