DEC 2 0 2002

K023554

GE Medical Systems
LUNAR

GE Lunar Corporation
General Electric Company
726 Heartland Trail, Madison, WI 53717
gemedicalsystems.com

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.

Contact Person:	James P. Raskob GE LUNAR Corporation 726 Heartland Trail Madison, WI 53717
Phone:	(608) 826-7425
Fax:	(608) 826-7825
Date:	October 22nd , 2002
Device/Trade Name:	Dual-energy Vertebral Assessment View Software Option
Common Name:	Bone Densitometer
Classification Name:	Bone Densitometer 21CFR 892.1170
Predicate Devices:	GE Lunar Lateral View software 510 (k) K000826 LUNAR EXPERT Morphometry Software 510(k) K950611 Hologic Morphometry II option 510(k) K992775

10.1 DESCRIPTION OF THE DEVICE:

The Dual-energy Vertebral Assessment View Software enables imaging of the spine for visual identification of vertebral deformities and estimation of vertebral heights (morphometry). Using this software, the patient is scanned as under the currently distributed product. The Dual-energy Vertebral Assessment View Option adds the ability to visually assess the image for identification of vertebral deformations.

10.2 CONCLUSION

The Prodigy Dual-energy Vertebral Assessment View Software is substantially equivalent to currently marketed software. No new safety and effectiveness questions are raised with the Dual-energy Vertebral Assessment View Software application.

Signed

James P. Raskob

Printed Name

Regulatory Affairs/Quality Assurance Manager

Title

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 0 2002

Mr. James P. Raskob
Regulatory Affairs/Quality
Assurance Manager
GE Lunar Corporation
726 Heartland Trail
MADISON WI 53717

Re: K023554
Trade/Device Name: Dual-energy Vertebral
Assessment View Software
Regulation Number: 21 CFR 892.1170
Regulation Name: Bone densitometer
Regulatory Class: II
Product Code: 90 KGI
Dated: October 21, 2002
Received: October 23, 2002

Dear Mr. Raskob:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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 Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, 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) K023554
- Device Name: PRODIGY Dual-energy Vertebral Assessment View Software
- Indications for use:

Dual-energy Vertebral Assessment View Software is used with the Prodigy bone densitometer. This software provides an x-ray image of the spine for qualitative visual assessment in order to identify vertebral deformations and estimate vertebral heights (morphometry).

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

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

(Optional Format 1-2-96)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K023554