

NOV 18 1997

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
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Date: July 3, 1997

Device/Trade Name: EXPERT-XL Orthopedic Hip Acquisition and Analysis Software

Common Name: Bone Densitometer

Classification Name: Bone Densitometer
21CFR 892.1170

Predicate Device: K914404 Orthopedic Software for Lunar DPX Series densitometers

10.1 DESCRIPTION OF THE DEVICE:

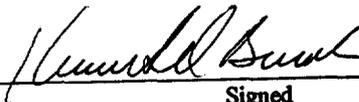
The Orthopedic Hip Acquisition and Analysis Software is an accessory software option for the EXPERT-XL Bone Densitometer that allows estimation of Bone Mineral Density BMD (in g/cm^2) of periprosthetic bone adjacent to an orthopedic hip implant.

10.2 SUMMARY OF TECHNICAL CHARACTERISTICS

Scans of the orthopedic hip region take 12 seconds. The EXPERT-XL Orthopedic Hip software results correlate highly ($r=0.97$) with DPX series, which already has 510(k) clearance. Also, the average short term precision (CV) in vivo is 3% or under for all sites, which is comparable to that shown on DPX series densitometers. The entrance radiation exposure to the skin of 53 mrem is higher than that for DPX series densitometers but remains low compared to the maximum permissible dose and to conventional radiographs of the region.

10.3 CONCLUSION

The BMD results for the EXPERT-XL Orthopedic Hip Acquisition and Analysis software option are comparable to the DPX results and have similar precision. No new safety and effectiveness questions are raised with the EXPERT-XL Orthopedic Hip Acquisition and Analysis software accessory.


Signed

Kenneth D. Buroker
Printed Name

Director, Regulatory Affairs
Title



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 18 1997

Richard B. Mazess, Ph.D.
President
Lunar Corporation
313 W. Beltine Highway
Madison, WI 53713

Re: K972517
Expert-XL Orthopedic Hip Acquisition and Analysis Software
Dated: October 7, 1997
Received: October 15, 1997
Regulatory class: II
21 CFR 892.1170/Procode: 90 KGI

Dear Dr. Mazess:

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 (Pre-market 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 INDICATIONS FOR USE FORM

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

The EXPERT-XL Orthopedic Hip Acquisition and Analysis Software is used with the EXPERT-XL Bone Mineral Densitometry system. This new software feature allows for estimation of periprosthetic BMD of an orthopedic hip implant in sub-regions called Gruen zones. These zones are a typical radiographic labeling technique for orthopedic hip implants.

The EXPERT-XL Orthopedic Hip Acquisition and Analysis Software requires a 12 seconds with an entrance radiation exposure to the skin of 53 mrem. This software poses no new safety or efficacy concerns.

The use on the EXPERT-XL Orthopedic Hip Acquisition and Analysis Software is restricted to prescription only. The User's Guide for the 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.

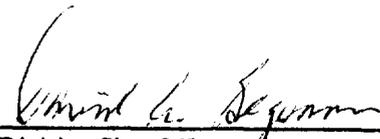
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(per 21 CFR 801.109)

or

Over-the-Counter Use

(Optional Format 1-2-96)



 (Division Sign-Off)
 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices
 510(k) Number K972517