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LUNAR

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K970224

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).

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Date: January 17, 1997

Device/Trade Name: PIXI Bone Densitometer

Common Name: Bone Densitometer

Classification Name: Bone Densitometer
21CFR 892.1170

Predicate Device: Osteon Osteoanalyzer
510 (k) K891582

Norland pDEXA
510 (k) K931996

10.1 DESCRIPTION OF THE DEVICE:

The PIXI Bone provides an estimation of Bone Mineral Density (BMD in g/cm^2) for the regions of the forearm and heel (os calcis).

10.2 SUMMARY OF TECHNICAL CHARACTERISTICS

The PIXI® Bone Densitometer requires a 5 second exposure, with a total exposure dose of 20 mrem. The radiation exposure of 20 mrem is higher than that for the predicate devices but remains low compared to the maximum permissible dose for extremities. The BMD estimations correlate highly (r= 0.998) with the actual density of calcium hydroxyapatite pellets. The average short term precision (%CV) in vitro was 0.68 %. The average short term precision (%CV) in vivo is 1.5% for forearm BMD, and 1.97 % for Os Calcis BMD. These values are comparable to those shown on previously cleared devices.

10.3 CONCLUSION

The results from the PIXI bone densitometer are comparable to previously registered devices which demonstrate similar precision. No new safety and effectiveness questions are raised with the PIXI Bone Densitometer.

Signed

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Title