

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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Device/Trade Name: EXPERT-XL Forearm and Hand Acquisition and Analysis Software

Common Name: Bone Densitometer

Classification Name: Bone Densitometer
21CFR 892.1170

Predicate Device: K915535 Forearm Software for Lunar DPX Series
K953032 Hand Software for Lunar DPX Series

10.1 DESCRIPTION OF THE DEVICE:

The EXPERT-XL Hand and/or Forearm Acquisition and Analysis Software is an accessory software option for estimation of Bone Mineral Density BMD (in g/cm^2) of the forearm and/or hand region provided for by the EXPERT-XL Bone Densitometer.

10.2 SUMMARY OF TECHNICAL CHARACTERISTICS

Scans of the forearm or hand region take about 10 seconds. The EXPERT-XL Forearm and Hand software results correlate highly ($r = 0.96$) with the corresponding regions measured on the DPX series, which already has 510(k) clearance. Also, the average short term precision (CV) in vivo is 2% or under for all sites, which is comparable to that shown on DPX series densitometers. The radiation exposure of 12 mrem is higher than that for DPX series densitometers but remains low compared to the maximum permissible dose to the extremities.

10.3 CONCLUSION

The BMD results for the EXPERT-XL forearm/hand software option are comparable to the DPX results and have similar precision. No new safety and effectiveness questions are raised with the EXPERT-XL forearm and hand software accessory.



Signed

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