

JUL 25 1996

## 8.0 510(K) SUMMARY

This summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 807.92(C).

**Re:** 510(k) Pre-market Notification

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**Date:** March 8, 1996

**Device Name:** EXPERT<sup>®</sup> Spine Morphometry Reference Values

**Common Name:** Spine Morphometry Reference Values

**Trade Name:** EXPERT Spine Morphometry Reference Values

**Classification Name:** 21 CFR 892.1170, Bone Densitometer

**Predicate Device:** EXPERT Spine Morphometry, 510(k) K950611

DPX Bone Densitometer, Reference Values  
510(k) K890121

## 8.1 DESCRIPTION OF THE DEVICE:

Reference values of spine morphometry have been added to the EXPERT Spine Morphometry Software. The addition of reference values does not change the intended use of the EXPERT Spine Morphometry Software. The reference value comparison results are used at the discretion of the physician.

**8.2 DISCUSSION OF PERFORMANCE DATA SUBMITTED IN SUPPORT OF THE SAFETY AND EFFICACY CLAIMS FOR THE DEVICE:**

Data from seven studies and over 3500 subjects have been used to provide normalized reference data for spine morphometry.

**8.3 CONCLUSIONS DRAWN FROM DATA:**

The addition of spine morphometry reference values does not raise any new questions of safety or effectiveness. The reference data is used at the discretion of the physician.

  
Signed

Gary Syring  
Printed Name

Director, Regulatory Affairs  
Title