ortho KINEMATICS
revolutionizing spine motion analysis

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Ortho Kinematics Receives FDA 510(k) Clearance for KineGraphVMA System

Innovative technology bridges diagnostic gap hampering spine surgeons for decades

AUSTIN, Texas – January 10, 2012 — Ortho Kinematics, a private company focused on revolutionizing spine motion analysis, announced receiving 510(k) clearance from the U.S. Food and Drug Administration for the KineGraph VMA™ (Vertebral Motion Analyzer) system. The KineGraph VMA system is designed to improve a test routinely prescribed by spine surgeons—the flexion/extension x-ray.

Flexion/Extension x-rays have remained the standard for quantifying spine function for over 60 years. The standard test provides only a rough approximation of spine function because it compares measurements, taken from X-ray images, of patients standing upright versus bending backward, forward, and sideways. The KineGraph VMA involves patented refinements that allow surgeons to view videos of vertebral motion that cover the entire range of spine bending instead of comparing just two x-ray "snapshots".

In addition, a much more expansive set of biomechanical measurements are produced and overlaid on the video images. By delivering a more complete and actionable diagnostic dataset, the KineGraph VMA can support more informed treatment decisions. This can all be accomplished without increasing the radiation exposure to the patient.

Dr. Antonio Castellvi, a spine surgeon with clinical experience using the KineGraph VMA, says "Spine biomechanics are very complex, and in many cases flexion/extension x-rays simply don't provide enough data. The KineGraph VMA allows for a more nuanced understanding of how each level of the spine is functioning by providing an expanded set of vivo spine biomechanical data." Dr. Castellvi continued, "In the future, this may open the door to new ways of factoring spine biomechanics into our surgical decisions."

Adam Deitz, CEO of Ortho Kinematics, says "We believe there is an opportunity to fundamentally improve the way spine pathology is assessed. Spine surgeons lack some functional diagnostic tools in comparison to other surgical specialties, such as cardiovascular surgeons, who have benefitted for decades from advanced functional tests like electrocardiogram (EKG), stress testing and angiography. With this 510(k) clearance, we can now begin to bridge this gap."

The company expects to make the KineGraph VMA commercially available in the United States starting in February, initially limiting access to a select group of the largest U.S. spine specialty hospitals.

Headquarters:
7004 Bee Cave Road, Building 3, Suite 315
Austin, Texas 78746
512.334.5490
www.orthokinematics.com
info@orthokinematics.com