Ortho Kinematics Receives FDA 510(k) Clearance to Expand into Cervical Spine

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Innovative VMA diagnostic technology now available for both back (lumbar) and neck (cervical) assessments

Ortho Kinematics, Inc. (OKI), a privately held healthcare diagnostic company focused on spine imaging informatics, announced receiving 510(k) clearance from the U.S. Food and Drug Administration to expand the VMA (Vertebral Motion Analysis) system beyond the lumbar spine, so that the system can be available for cervical spine (neck) assessments as well.

The VMA system is a revolutionary new diagnostic technology that is an alternative to a test that has been routinely prescribed for the assessment of spinal instability for over 70 years. Spinal instability is a condition that very often results in severe back and neck pain, and is the number one most common primary diagnosis driving the 500,000+ spine fusion surgeries done in the US each year.

The VMA offers patients and physicians considering spine surgery a valuable testing alternative, and has been shown in clinical studies to identify spinal instability that may be difficult to detect. As a result, VMA testing can help doctors identify a very common and treatable pathology that may be difficult to detect with the currently available test.

Paul Gunnoe, CEO of Ortho Kinematics, Inc., said, "For many lumbar patients, VMA testing has made the difference in getting the right diagnosis to successfully treat unrelenting, debilitating back pain. With the clearance of the cervical VMA system, we are very happy to now offer this same opportunity to patients with neck problems as well."

Dr. David Lee, a spine surgeon user of the VMA lumbar system, said, "I have seen for myself cases where the VMA has been the only test capable of providing the evidence demanded by insurance companies to approve coverage for lumbar surgery. With the new cervical system, I can now offer this valuable option to my neck pain patients as well."

VMA testing is now available at a select set of leading spine surgery centers. A large scale national roll-out is scheduled for early 2014.

About Ortho Kinematics

Ortho Kinematics is a privately held diagnostic technology company, focused on spine imaging informatics and committed to the idea that spine motion matters. The company is working with a group of leading clinicians, researchers and developers who are passionate about leveraging spine biomechanical data to improve the diagnosis and treatment of back pain. Ortho Kinematics is located in Austin, Texas and is on the web at www.orthokinematics.com. For more information contact Ortho Kinematics, Inc. at info@orthokinematics.com.

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