



PRESS RELEASE 4/06/16

Ortho Kinematics Becomes ISO 13485-Certified and Clears FDA Audit

The company's commitment to quality is now verified by two independent authorities.

AUSTIN, Texas – April 6th, 2016 — Ortho Kinematics, Inc. (OKI), a privately held healthcare diagnostics company focused on spine imaging informatics, today announced it has received ISO 13485:2003 certification, an internationally recognized quality standard for medical devices. Separately earlier this month, the FDA completed a Level I inspection of the company's facilities. This inspection resulted in no Form 483 observation letters, which are issued by the FDA if an audit uncovers non-conformities with a company's quality systems.

OKI CEO Paul Gunnoe said, "We are very pleased to achieve the high standards for quality set forth by expert bodies like the FDA and the International Standards Organization (ISO)." Mr. Gunnoe continued, "We have built a solid foundation for operational expansion, which will be critical to our success as we race to keep pace with the increasing demand for the VMA technology." OKI has seen an explosion in demand over the past 6 months, and has more than tripled the VMA's install base in addition to accumulating a large backlog of clients awaiting fulfillment. Among the adopting sites are some of the world's most prestigious spine surgery institutions.

The company's lead product, VMA, is a diagnostic test for the assessment of spinal motion and radiographic instability. Today's current test for assessing spinal radiographic instability is ordered over 5 million times per year in the US, largely by spine surgeons, because it provides diagnostic data that is necessary for many patients being considered for potential spine surgery. The VMA has been shown in peer-reviewed studies to increase the sensitivity in detecting radiographic instability with no decrease in specificity relative to today's current standard test. It has also been shown to be more accurate, repeatable, and result in a lower dose of radiation.

Dr. Stephen David, a spine surgeon and a new VMA user, said, "the VMA's expanded and improved set of measurements can be very enlightening, and routinely change treatment decisions." Dr. Stephen David continued, "This has shown me that before I started using the VMA, I was only getting part of the picture regarding radiographic instability."

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 at www.orthokinematics.com.