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SpineWorks Medical, Inc. Announces CE-Mark for SpineAlign™ Vertebral Body Replacement System

SAN JOSE, CALIF.-- July 15, 2008 – SpineWorks Medical, Inc. announced today that it received CE-Mark authorization for commercialization of its SpineAlign™ Vertebral Body Replacement (VBR) System in the European Union and all countries recognizing the CE-Mark. The SpineAlign VBR is SpineWorks Medical's first approved product that was designed for a transpedicular, minimally-invasive approach to vertebral body reconstruction and anterior spinal column support.

The SpineAlign VBR was subjected to a series of ASTM tests conducted in accordance with the FDA "Guidance for Industry and FDA Staff: Spinal System 510(k)s" document issued May 3, 2004. "We completed all of the recommended biomechanical testing in compliance to the VBR guidance standards and exceeded all recommended loads," stated Paul Chirico, President and CEO for SpineWorks Medical. "Our product development process has incorporated a diligent approach of keeping an eye on the biomechanics that are needed to accomplish this exciting new approach to reconstructing disease and age compromised vertebral bodies."

"In the delivery of care for spinal diseases, physicians are always looking for more innovative technologies -- especially those that utilize the latest generations of medical imaging to deliver more effective therapies," said Sean Pakbaz, MD, Associate Professor of Radiology and Neurointerventional Surgery at the University of California San Diego Medical Center and consultant to SpineWorks Medical. "The SpineAlign device which has surpassed our expectations in both laboratory and cadaveric testing allows us to work directly through the spine vertebral body pedicle, while at the same time minimizing soft tissue disruption. To reconstruct a vertebral body is becoming easier, both for us, and for the patient."

The SpineAlign device represents the first of many new innovations in the area of minimally invasive percutaneous vertebral body reconstructions to come from SpineWorks Medical. The treatment of spine disease is rapidly moving from open surgery toward less tissue disruptive procedures with the use of better imaging and innovative, minimally invasive devices.

SpineWorks Medical, Inc., is an early-stage medical device company dedicated to the design, development and successful commercialization of minimally-invasive products for spine procedures. SpineWorks Medical currently has products under review by the FDA and anticipates having several CE-Marked products cleared for European commercialization by the end of 2008.