Precision Spine™ Announces FDA 510(k) Clearance for its Mini-Max™ Minimally Invasive Access System

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December 11, 2012 – Parsippany, NJ – Precision Spine announced today that it received 510(k) clearance from the FDA on November 20, 2012 for its **Mini-Max Minimally Invasive Access System**.

The addition of the **Mini-Max Minimally Invasive Access System** to the company's expanding array of minimally invasive spinal solutions will enable spine surgeons to perform minimally invasive procedures using a versatile "access/fixation" system that has been designed to achieve results using a minimally disruptive procedure, that are the same as or better than those achieved using the "gold standard", open procedures.

The new system has been designed to offer several distinguishing features and benefits as compared with currently available minimally invasive surgery (MIS) systems. It uses techniques that are familiar to surgeons, potentially shortening any learning curve and reducing operative time. Its hardware and corresponding procedural steps are configured to facilitate greater direct visualization of the spine and easier access to the contralateral side and levels above and below the target level. In eliminating the need to remove the screw tulip head during assembly, the design team sought to reduce "fiddle factor" as well as the overall number of procedural steps. The system's muscle sparing technique, contrasted with percutaneous approaches that puncture muscle, is anticipated to speed recovery time and improve patient outcomes. The design team focused on enabling more easily achieved procedure-to-procedure reproducibility, with the goal of enhancing cost-effectiveness for hospitals and payers.

The Mini-Max System is intended for use with the company's **S-LOK™ Pedicle Screw System**. The S-LOK System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

The S-LOK System is also intended for non-cervical pedicle screw fixation for the following indications: severe spondylolisthesis (grades 3 and 4 of the L5-S1 vertebra) in

skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion. It is also intended for the following indications: trauma (i.e., fracture or dislocation), spinal stenosis, curvatures (i.e., scoliosis, kyphosis, and/or lordosis), spinal tumor, pseudarthrosis, and failed previous fusion.

Dr. Donald Kucharzyk, Director of the Minimally Invasive Spine Surgery Institute (Crown Point, Indiana) and lead development surgeon for the new system commented, "The development of the **Mini-Max Minimally Invasive Access System** represents what we believe to be the next evolutionary step in the ongoing advancement of MIS spine procedures. I believe that the incorporation of "minimally disruptive techniques" familiar to spine surgeons, along with the ability to facilitate "maximum access" through very small incision sites gives the new system significant advantages over the currently existing MIS spine systems now on the market. The development of this system was driven by our desire to make available to spine surgeons an MIS system that results in less surgical trauma to the patient, utilizing known muscle sparing techniques with resultant better patient recovery and outcomes. The system is expected to allow the achievement of those desired benefits, and to enable surgeons to perform everything that is possible through a classic open approach, but less invasively and with less disruption."

Rich Dickerson, President of Precision Spine, stated, "We believe that the first phase launch of the **Mini-Max Minimally Invasive Access System** represents a significant advancement in minimally invasive approaches to spine surgery. We are planning to make the system available in two phases. Phase 1, the base system, will enable pedicle screw-based tissue retraction and distraction for maximal access to the disc space. Phase 2, the additional system components, will enable parallel, bilateral distraction of vertebral bodies to facilitate even more effective placement of an advanced interbody device, which is now in the development phase. The company's commitment to research and product development continues to bear fruit with products such as the **Mini-Max Minimally Invasive Access System**, that offer unique advantages to surgeons, patients, hospitals and payers, and that are helping to differentiate us from our competition. The advanced interbody device and additional products with designs that are optimized for use with the new system are in development now, and will further enhance the potential benefits of this new approach to MIS spine surgery."

About Precision Spine

Precision Spine, Inc., the parent company of Spinal USA, Inc., is a privately held company headquartered in Parsippany, New Jersey, with manufacturing facilities in Mississippi. Precision Spine is dedicated to providing innovative, quality spine products that are designed to help treat serious orthopedic medical conditions in a cost effective manner. For more information, visit www.precisionspineinc.com.