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Precision Spine™ Announces FDA 510(k) Clearance for ReForm™ Pedicle Screw System

September 25, 2012 – Parsippany, NJ – Precision Spine, Inc. announces that it received 510(k) clearance from the FDA on August 8, 2012 for the ReForm Pedicle Screw System.

The ReForm Pedicle Screw 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 thoracic, lumbar and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudarthrosis).

The ReForm Pedicle Screw 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 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; and failed previous fusion.

The addition of the ReForm Pedicle Screw System to the company's broad and expanding array of quality spinal solutions offers surgeons a versatile correction system that can be applied to multiple levels throughout the thoracic, lumbar and sacral spine. The system offers new and innovative polyaxial and uniplanar pedicle screw designs, both of which incorporate a triple lead thread and cobalt chrome tulip head. Both titanium and cobalt chrome rods are included, as well as titanium cross connectors. The ergonomic instrument set features a strong yet versatile reduction and de-rotation tower system. With ReForm, spine surgeons can have the advantage of strength without compromising the versatility of a low profile design.

Dr. Rudolph Taddonio, Director of Orthopedic Surgery at Stamford Hospital in Stamford, Connecticut, and Professor of Scoliosis and Spinal Surgery at New York Medical College, participated in the development of the new system. After evaluating the final design, he commented, "The development of the ReForm Pedicle Screw System represents a metamorphosis in pedicle screw, rod and instrumentation technology, which will increase its efficiency of application and ease of ergonomic use, and as a result, will help promote patient safety. Precision Spine's product development team for this system has had years of experience with pedicle screw systems and has put a great deal of time and thought into this design. I believe it will be recognized as one of the most useful deformity correction systems available to the spine surgeon community when it launches later this year."

Rich Dickerson, President of Precision Spine, stated, "We are excited about the addition of the ReForm Pedicle Screw System to our product offerings. Our ongoing focus on research and product development continues to result in new product offerings such as ReForm, which we believe will present a compelling option to surgeons seeking versatile technologies to treat spinal pathologies."

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.