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Precision Spine® Receives FDA 510(K) Clearance for the Dakota ACDF™ Standalone System

February 4, 2021 - Parsippany, NJ – Precision Spine, Inc., a medical device company dedicated to Made-in-the-USA manufacturing, announced today that it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for the Dakota ACDF™ Standalone System in the treatment of degenerative disc disease (DDD). The Dakota ACDF system features a titanium plate polyetheretherketone (PEEK) cage with cortical cancellous screws for maximum support and a generous cavity for autogenous bone graft to help facilitate fusion.

"With the inclusion of differentiating dual thread screws and high screw angulations, the Dakota ACDF system offers superior fixation and stability," said Payam Farjoodi, MD from Coastline Orthopaedic Associates in Fountain Valley, CA. "The unsurpassed ease of use provided by the intuitive instrumentation makes it an ideal system for even the most challenging cases."

"The Dakota ACDF System represents another example of how Precision Spine is making good on its commitment to develop surgeon-designed devices that embody the advanced features surgeons need to help improve OR efficiency and achieve positive patient outcomes," said Chris DeNicola, Chief Operating Officer of Precision Spine.

The Dakota ACDF System is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine (C2-T1) at one or two disc levels with DDD defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. The device is placed via an anterior approach at the C2 to T1 disc levels. Patients should have at least six weeks of non-operative treatment prior to treatment with an intervertebral fusion device such as the Dakota ACDF System.

About Precision Spine
Precision Spine, Inc. is a privately held company headquartered in Parsippany, NJ with manufacturing facilities in Pearl, MS. Precision Spine is dedicated to providing innovative, quality spine products that are made in the USA and designed to help treat serious orthopedic medical conditions in a cost-effective manner. For more information, visit www.precisionspineinc.com.