SVB Financial Group

Financing; N Spine Receives 510(k) Clearance of Its NFix II Dynamic Stabilization System for the Lumbar Spine

March 5, 2007 — (NewsRx.com) — N Spine, Inc., a privately held San Diego spinal implant company, announced that it has received FDA clearance of its NFix™ II dynamic pedicle screw and rod system for stabilization of the lumbar spine as an adjunct to fusion. NFix™ II is now commercially available in the United States.

"Interest from US surgeons in the NFix™ II Dynamic Stabilization System has been extremely strong," said Sean Na, president and chief executive officer of N Spine. "This enthusiasm reflects the appeal of our unique design as well as the growing market adoption of dynamic rod systems."

Outside of the US, early clinical results with the company's NFlex™ Controlled Motion System have been very favorable. NFlex™ is the first product to market that controls shear motion, while allowing a more physiologic level of flexion, extension and lateral bending. NFlex™ is CE marked for non-fusion indications, and is the subject of an N Spine sponsored prospective randomized trial comparing it to the Zimmer Dynesys® device.

"I'm very pleased with the results of the three-month motion x-rays on the first NFlex™ patients," stated Hansen Yuan, MD, who is a member of the N Spine, Inc. Scientific Advisory Board. "It's clear that motion is maintained."

With clearance of the NFix™ II Dynamic Stabilization System for fusion surgery, and NFlex™ as a stand alone motion preservation device for non-fusion outside the US, the company is well positioned to leverage its proprietary designs in the $5 billion spinal implant market. "There are a significant number of patients who will benefit from motion preserving technologies," stated Na.

Recently, N Spine closed on $2.75 million debt financing by Silicon Valley Bank and has raised a total of $7.1 million in equity and non-dilutive financing.