

## **FDA Grants Conditional Approval to Interventional Spine's PercuDyn™ System IDE Application**

**Irvine, CA – Tuesday, July 1, 2008**, -- Interventional Spine, Inc. announced today that the U.S. Food and Drug Administration has approved the Company's investigational device exemption (IDE) application for its PercuDyn System for the treatment of degenerative disc disease (DDD). This approval is conditional upon the Company providing some additional information to the FDA.

Walter A. Cuevas, Interventional Spine's CEO observed, "We are pleased by FDA's action. We believe that the PercuDyn System is the first and only product of its kind, and we look forward to a day when it can be marketed in the U.S. as it already is in international markets. To that end, we now move to the next phase in the FDA approval process in gathering the data required for submission and pre-market approval."

Mr. Cuevas continued: "Today, patients in the U.S. with chronic, debilitating lower back pain resulting from disc degeneration typically have two basic choices for treatment. The first is Conservative Care, which includes weight loss, exercise, chiropractic manipulation, and steroid injections; the second is Fusion Surgery, with the attendant complications of open surgery, extended post operative rehabilitation, and cost. We believe our PercuDyn System offers these patients a new and potentially less traumatic therapeutic option – a PERCUTANEOUS intervention. We look forward to working with the FDA in establishing the data-based documented framework that will allow this technology to be added to the continuum of care."

"In markets outside the U.S. the PercuDyn System is chosen clinically by patients and their physicians when conservative care fails. The results we have seen so far show that patients treated with PercuDyn have less pain in a significantly shorter period of time with noticeably less trauma and complications as compared to open fusion surgery. As a result, patients treated with the PercuDyn System can resume normal activities within days, rather than months, almost immediately after the PERCUTANEOUS intervention. Also, the PercuDyn System usually is implanted in an outpatient setting, eliminating the cost associated with pre- and post-operative hospital stays."

"The PercuDyn System is being used in International Markets and has the CE Mark of approval for marketing in those countries where the Mark is recognized. Thus far, in these countries the PercuDyn System has shown significant advantages over conventional forms of treatment" concluded Mr. Cuevas.

Interventional Spine, Inc. is a privately held company based in Irvine, California that designs, develops, and markets patented implantable devices for the spine that can be deployed via percutaneous techniques, supported by the Company's unique product introduction systems, providing benefits to patients, surgeons, and hospitals. More information on the Company and its products can be found at: [www.i-spineinc.com](http://www.i-spineinc.com).

### **FOR FURTHER INFORMATION CONTACT:**

Walter Cuevas  
Chief Executive Officer  
949-472-0006