VertiFlex®, Inc. Announces FDA Clearance of Two Key Additions to Technology Portfolio

The Associated Press

SAN CLEMENTE, Calif.--(BUSINESS WIRE)--Jan 8, 2013--VertiFlex®, Inc., a leading innovator of advanced minimally invasive spinal surgery technologies , today announced FDA 510(k) clearance of two new products to its portfolio: The Totalis™ Direct Decompression System and UniVise™ Spinous Process Fixation System.

“These regulatory clearances represent important milestones for VertiFlex® as we rapidly expand our portfolio of innovative interspinous technologies,” said Earl R. Fender, President and Chief Executive Officer of VertiFlex, Inc. “We leveraged the unique benefits of our Superion® Interspinous Spacer System and strong IP position, to develop these differentiated products to address two significant market opportunities. This accomplishment highlights the company’s core strengths and fundamental commitment to provide physicians with multiple options to best treat patients in the least invasive methods possible.” The Totalis™ Direct Decompression System is a unique set of surgical instruments designed specifically for performing minimally invasive direct decompressions of the lumbar spine. The system utilizes VertiFlex’ proprietary interspinous access platform and includes both reusable and disposable instruments to treat spinal stenosis by removing targeted bone and soft tissue. The Totalis™ Direct Decompression System was 510(k) cleared by the FDA in November, 2012.

The UniVise™ Spinous Process Fixation System is a spinal implant system designed to provide fixation of the spinous processes as an adjunct to lumbar spinal fusion. The system leverages the company’s core technology and intellectual property. The UniVise™ system is the least invasive spinous process fixation system available and was 510(k) cleared by the FDA in December, 2012.

The Superion® Interspinous Spacer System (ISS) is a motion-preserving spinal implant system for the treatment of moderate lumbar spinal stenosis. Superion® is the most advanced and least invasive ISS available or in development for performing indirect decompressions of the lumbar spine. The Superion® implant is delivered from a posterior midline approach through a proprietary interspinous access system developed by VertiFlex®. The small incision can be closed with a single suture and performed under local anesthesia on an outpatient basis. Once in place, it may reduce pressure on the nerves that cause pain and allow the return to a more active lifestyle. Superion® has been CE marked since 2007 and is currently an investigational device in the U.S. Enrollment completed in the Superion® pivotal IDE trial with 470 patients in December, 2011. It has been implanted in over 2000 patients worldwide.

About VertiFlex®, Inc. VertiFlex® is a privately held medical device company dedicated to the advancement of minimally invasive solutions for the treatment of

lumbar spinal stenosis, which is the leading cause of spinal surgery in the elderly. Founded in 2005 and headquartered in San Clemente, CA, VertiFlex® has developed a proprietary, minimally invasive interspinous access platform for performing both indirect and direct decompressions of the lumbar spine. These technologies fill the MIS procedural gap in the stenosis treatment continuum between conservative care and traditional spine surgery. This provides new options for interventional spine physicians and less invasive options for traditional spine surgeons to treat patients who would otherwise undergo more invasive surgery. To date, VertiFlex® has compiled the largest, most rigorous, body of device clinical evidence, related to lumbar spinal stenosis.

CONTACT: VertiFlex®, Inc.

Scott Lynch 949-940-1400 info@vertiflexspine.com www.vertiflexspine.com KEYWORD: UNITED STATES NORTH AMERICA CALIFORNIA INDUSTRY KEYWORD: SURGERY HEALTH MEDICAL DEVICES FDA SOURCE: VertiFlex, Inc. Copyright Business Wire 2013 PUB: 01/08/2013 11:05 AM/DISC: 01/08/2013 11:05 AM http://www.businesswire.com/news/home/20130108006523/

Source URL (retrieved on *01/25/2015 - 11:18am*):
http://www.mdtmag.com/news/2013/01/vertiflex%C2%AE-inc-announces-fda-clearance-two-key-additions-technology-portfolio?qt-video_of_the_day=0&qt-most_popular=0