

Press Release

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FOR IMMEDIATE RELEASE
9:00 AM EDT, June 5, 2007

VERTEBRATION'S XYCOR™ SPINAL IMPLANT RECEIVES FDA 510(K) CLEARANCE

POWELL, OHIO, JUNE 5, 2007: Vertebration™, Inc., a developer, manufacturer and marketer of minimally invasive spinal implant systems, synergistic spinal solutions and instrumentation, announces the clearance of the XYcor™ Spinal Implant by the U.S Food and Drug Administration through a 510(k) application. The XYcor™ Spinal Implant is an expandable implant, giving surgeons an extremely low-profile solution to the anatomic constraints of minimally invasive surgery. For insertion, the XYcor™ requires one-half the intradiscal entry point, but once deployed has a footprint comparable to traditional anterior interbody/VBR devices.

The XYcor™ Spinal Implant is specifically designed for low profile, minimally invasive implantation and is compatible with all current MIS/MAST (Minimally Invasive Surgery/ Minimal Access Spinal Technique) access systems. The XYcor™ Spinal Implant is delivered via a minimal access posterior/posterolateral annulotomy that is no larger than that used for a standard microdiscectomy. The implant is designed to restore and maintain biomechanical integrity throughout the thoracolumbar spine following vertebrectomy or corpectomy for patients with spinal tumors or fractures. The implant, together with supplemental rigid internal fixation, provides anterior, middle and posterior column support both immediately after surgery and for prolonged periods in the absence of bone fusion. The implant is a cross-limbed, expandable vertebral body replacement device manufactured from surgical grade titanium.

In its collapsed state, the implant minimizes the cross-sectional area and allows for improved minimally invasive delivery to the level of the vertebral body. Once appropriately positioned, the XYcor™ Spinal Implant is expanded to the deployed state maximizing the cross-sectional area or footprint, there by maximizing mechanical stability and enhancing potential bony ingrowth and fusion.

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XYCOR™ SPINAL IMPLANT RECEIVES FDA 510(K) CLEARANCE - PAGE 2 -

The XYcor Spinal Implant is available in eight different heights based on 1 mm increments. Currently, there are 64 models of the implant approved under the recent 510(k) application. Several key characteristics of the XYcor™ Spinal Implant include:

- biomechanics comparable, or exceeding those of solid geometry anterior and posterior interbody fusion devices and vertebral body replacement devices.
- enhanced volume and porosity available for graft material, in most cases more than twice that of currently approved anterior and posterior implants;
- design achieves modulus of elasticity superior to implants offered in PEEK and comparable to bone.

“The XYcor™ Spinal Implant is the first in the family of implants Vertebration has under development focused on enabling spine surgeons to extend their minimally invasive options for thoracolumbar spine surgery,” said Richard Karr, President of Vertebration™, Inc. "With Columbus' strengths in medical product innovation, Vertebration offers an exciting new technology to combat a troubling area of spinal conditions and back pain. The young company's success has been due to the fact that they have assembled all the right pieces. The need is great, the market is huge, the technology is sound, and the leadership team, comprised of several alumni from the Fisher Executive MBA, is poised for rapid market penetration and growth," said Michael Camp, Academic Director, Center of Entrepreneurship, Fisher College of Business, The Ohio State University.

About Vertebration, Inc.

Vertebration, Inc., develops, commercializes and markets minimally invasive spinal implant systems and synergistic spinal solutions and instrumentation. Based in Powell, Ohio, the company was founded in 2004. The company's business plan won the Deloitte Business Plan Competition in May of 2004 at the Fisher College of Business and the Fortune Small Business MBA Showdown Business Plan Competition in October 2004. Vertebration, Inc. is lead by Dr. Henry Fabian, Jr., Co-founder and Chief Executive Officer, and Mr. Richard Karr, Co-founder, President and Chief Operating Officer.

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