Spine Wave Announces U.S. FDA's 510K Clearance of the StaXx® IB System, an Intervertebral Body Fusion Device

The StaXx® IB System expands the StaXx® product portfolio and offers the advantage of an Expandable Intervertebral Body Fusion Device with Bone Graft Chambers

SHELTON, CT – April 29, 2013 – Spine Wave, Inc. a privately held medical device company committed to the development and delivery of high-quality innovative medical devices for the treatment of spinal disorders, today announced that it has received 510(k) clearance from the United States Food and Drug Administration to market and sell the StaXx® IB System, an Intervertebral Body Fusion Device. The StaXx® IB System leverages Spine Wave's well established ability to produce expandable PEEK spacers and now for the first time offers an expandable device with bone graft chambers. The Company will be previewing the device at the American Academy of Neurosurgeons meeting in New Orleans.

"We are pleased to be able to offer the StaXx® IB System as the latest product in our innovative and highly differentiated portfolio of technologies," said John Pafford, Spine Wave Chief Technology Officer. "This is the first of several exciting products we expect to introduce over the next twelve months as we strive to deliver important and novel clinical solutions for spine surgeons."

About Spine Wave

Spine Wave's product portfolio features many highly differentiated technologies including the flagship product, the StaXx® XD Expandable Device, which has a five year proven track record for posterior surgery. The StaXx® XD family of products also includes StaXx® XDL which is intended to be implanted using a lateral surgical approach. In addition to the expandable technologies, the Sniper® Spine System has quickly developed a reputation as a leading MIS screw system and the simple yet versatile CapSure® PS3 Spine System is proving to be a high quality, traditional screw system with a recently expanded offering for complex surgery. The Company is growing rapidly and continues to recruit new sales managers and independent distributors to fuel the growth. The Company also continues to advance the NuCore® Injectable Nucleus technology in a European clinical trial designed to treat early stage DDD via a percutaneous injection. For further information on all of the Spine Wave products please visit the Company's website at www.SpineWave.com.

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