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Spinal Elements® Receives 510(k) Clearance for Expandable Interbody Device

CARLSBAD, CA – June 20, 2016 – Spinal Elements, a spine technology company, announced that they have received 510(k) clearance from the United States Food and Drug Administration (FDA) to market a line of expandable interbody fusion devices.

A comprehensive list of items were a part of this clearance, including expandable interbody devices for posterior, anterior, and lateral access to the lumbar spine. The expandable interbody devices are placed in the intervertebral space of the spine at a collapsed height and expanded vertically to increase in height. Additionally, the posteriorly-placed and anteriorly-placed devices can increase in lordotic angle during expansion, and the laterally-placed devices can change coronal (side-to-side) tilt during expansion.

The expandable devices will be made primarly from radiolucent PEEK material and feature Spinal Elements' Ti-Bond® porous titanium coating at the endplate contacting surfaces. PEEK has material properties that allow it to be a more load-sharing material in comparision to other popular implant materials such as titanium alloy. Spinal Elements' Ti-Bond coating has been successfully used since 2012 in almost 10,000 implants and offers a roughed titanium surface for contacting the vertebral endplates.

Dr. Hyun Bae, Medical Director at The Spine Institute and Professor of Surgery at Cidars-Sinai Medical Center in Los Angeles, commented, "I'm excited to get this device into a clinical setting as I believe the application of the device will help me address the needs of my patients. The ability of the device to expand as well as increase lordosis post-implantation will help me achieve saggital balance from a posterior approach unlike other devices I've experienced."

Jason Blain, President and co-founder of Spinal Elements, added, "We believe the market for expandable interbody devices will continue to grow and the devices that were cleared will allow us to continue to grow our portfolio of proprietary solutions for our customers. While these expandable devices will work well with our conventional spine surgery platforms, we also believe they will complement our MIS procedural options as well, as we look to increase our presence in posterior MIS solutions."

The company plans to begin clinical procedures with the expandable devices later this year with an initial launch in early 2017.

About Spinal Elements

Spinal Elements, headquartered in Carlsbad, CA, is a spine technology company for spine surgeons who demand innovative, extremely high quality surgical solutions. From the company's early work which helped make PEEK commonplace throughout the spine industry to recent advancements in Ti-Bond® porous titanium coated PEEK interbody implants and controlled delivery technology, Spinal Elements has built a reputation for being trustworthy, innovative and different. The company is focused on the development and marketing of progressive spinal treatment options and markets a complete portfolio of advanced spinal implant technologies. Additionally, the company distributes Hero® Allograft, the net proceeds from which are donated to charities benefitting children with life-threatening medical conditions. For more information, please visit www.spinalelements.com.

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