PARADIGM SPINE RECEIVES FDA PRE-MARKET APPROVAL (PMA) FOR FIRST OF ITS KIND DISPOSABLE INSTRUMENT KIT

Marks first approved disposable spinal instrument set for a Class III spinal device

NEW YORK, NY May 2, 2018

Paradigm Spine, LLC, a leader in providing motion preservation solutions for the treatment of lumbar spinal stenosis, today announced that the U.S. Food and Drug Administration (FDA) has granted pre-market supplemental approval (PMA) for its coflex® Interlaminar Stabilization® disposable instrument kit. This marks the first approved disposable spinal instrument set for a Class III spinal device to receive a supplemental PMA approval, the most stringent type of device marketing application required by FDA.

coflex® Interlaminar Stabilization is Paradigm's signature product and the exclusive posterior lumbar motion preservation solution with proven long-term outcomes for patients with moderate to severe spinal stenosis. The newly approved coflex disposable instrument kit offers a future additional option for implantation of coflex that is ideal in the outpatient setting of care. The kit will consist of a complete and simplified set of injection molded instruments delivered in a pre-sterilized peel pack.

"As a frequent user of coflex and experienced developer of several spinal disposable instrument sets, I am excited to have an additional resource approved for these procedures," said neurosurgeon Richard N.W. Wohns, MD, JD, MBA, founder and president of NeoSpine, LLC in Puyallup, Washington. "Having a disposable coflex surgical kit will be ideal for simplifying and streamlining our operating room activities, particularly in ambulatory surgery centers. It's a great value proposition to have reliable availability of instruments that are guaranteed sterile, saving labor costs in preparation time, increasing efficiency in the operating room, and diminishing potential infection risk vs. traditional reusable instruments."

"We are thrilled to have the first PMA-approved disposable instrument kit for a Class III spinal device, and be able to offer this resource to our surgeon customers, further improving their experience with coflex," said Marc Viscogliosi, Chairman and CEO of Paradigm Spine. "These kits are ideal for outpatient and ambulatory surgery centers because they are simple, disposable, sterile, and will reduce both financial and operational burdens on facilities. In addition, through a more streamlined manufacturing process, the kits are created to have a low carbon footprint, so they benefit physicians without causing excessive harm to the environment."

About Lumbar Spinal Stenosis (LSS)

Lumbar spinal stenosis (LSS), affecting 1.6 million patients annually in the United States, is a debilitating and degenerative disease often associated with significant leg and back pain, leg numbness and weakness, and significant reduction in an active lifestyle. Historically, the two traditional surgical treatment options for LSS included decompression alone or decompression with lumbar fusion. Decompression alone has proven effective at relieving pain symptoms caused by lumbar spinal stenosis, however, patients may not experience long term symptomatic relief, resulting in subsequent epidural injections for pain management, or additional surgeries for conversion to a fusion. Decompression with fusion has proven to provide pain relief and stabilize the diseased segment, but may lead to adjacent level disease requiring subsequent surgeries.

About Paradigm Spine, LLC:

Paradigm Spine, LLC, founded in 2004, is a privately held company and remains focused on the design and development of solutions for the disease management of spinal stenosis. The Company's signature product is the *coflex*® Interlaminar Stabilization® device, which is currently used in over 60 countries worldwide. coflex is the only lumbar spinal device that has produced Level I evidence in two separate prospective, randomized, controlled studies against two different control groups, changing the standard of care for lumbar spinal stenosis treatment. For additional information visit www.paradigmspine.com or www.coflexsolution.com.

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