NLT SPINE's PROW FUSION™ and eSPIN™ Receive 510(k) Clearance

Kfar Saba, Israel, October 30, 2013 – NLT SPINE, a developer of less invasive spine procedures, announced today that two of its generation 2.0 products designed for spinal fusion procedures received 510(k) clearance from the U.S. Food and Drug Administration (FDA).

PROW FUSION™ and eSPIN™ both target the lumbar interbody fusion market, which currently represents an opportunity of approximately $1.3 billion globally. Both products are already in clinical use in Europe.

PROW FUSION™ Interbody Fusion device and delivery system are intended for spinal transforaminal lumbar interbody fusion procedures (TLIF). The product was developed based on NLT SPINE's non-linear core technology which allows for inserting large implants and instruments through a small incision. The FDA has already cleared the previous version of the device, however generation 2.0 offers enhanced design, new material, and fewer instruments required to perform the procedure.

eSPIN™ is intended for use in cutting and grinding intervertebral disc material during discectomy for fusion procedures. Similarly to PROW FUSION™, the previous version of eSPIN™ has been cleared by the FDA, and generation 2.0 enhancements include an additional irrigation capability, and optimized cutting tips design.

"The FDA clearance for two of our products strengthens our drive and commitment to continue and innovate to offer surgeons and patients a differentiated experience in less invasive spine procedures". Said Didier Toubia, NLT SPINE's CEO.

"Alongside a strong intellectual property and FDA clearance for these two leading products, our platform becomes a solid offering in this market. With additional products in our pipeline, we plan to quickly address most of the major segments of the spinal implants business, a $7.6B opportunity worldwide".

Dr. Uri Geiger, Chairman and Managing Partner at Accelmed, the main investor in NLT SPINE, added: "PROW FUSION™ 2.0 approvals and the strong product pipeline, strengthens NLT SPINE positioning as a leading innovator in the minimally invasive spine landscape. Combining this kind of break-through platform based on Israeli Innovation with a strategic partner with a solid US commercial infrastructure is now a viable option, and Accelmed will support such an initiative".

For more information about NLT SPINE and its technology please visit http://www.nlt-spine.com

About NLT SPINE
NLT SPINE specializes in the development of innovative spine surgery instrumentation and implants for treating degenerative spinal conditions through small surgical incisions. The company's vision is to improve patient care and reduce total treatment costs by ultimately shifting from traditional open surgical routines to minimally invasive procedures employing new methods and technologies to enhance usability and outcomes.

Led by top international leaders in spinal surgery, NLT SPINE holds a wide portfolio of pending and issued patents that cover the non-linear core technology and related implant and instrument technologies.

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