NLT SPINE Receives 510(k) Clearance for its Discectomy System, eSPIN™

The Associated Press

KFAR SABA, Israel--(BUSINESS WIRE)--Sep 20, 2012--NLT SPINE, a developer of products for Minimally Invasive Spine Surgery (MISS) and percutaneous procedures, announced today that its eSPIN powered discectomy system has received 510(k) clearance from the U.S. Food and Drug Administration (FDA).

eSPIN is intended for use in cutting and grinding intervertebral disc material during discectomy for fusion procedures in L2-S1 spinal segments in skeletally mature patients with degenerative disc disease (DDD). DDD patients may also have up to Grade I Spondylolisthesis or retrolisthesis at the involved levels. The device, together with PROW FUSION, is intended to be used with supplemental spinal fixation systems that have been cleared for use in the lumbosacral spine (i.e. posterior pedicle screw and rod systems).

The system bears CE Mark and has been successfully used in Europe.

eSPIN addresses several challenges associated with manual disc preparation instruments. NLT SPINE demonstrated the following benefits of eSPIN: Significant disc evacuation in the contra-lateral side of the disc 67% more disc volume removed compared to standard instruments 83% fewer instrument passes by the exiting nerve “eSPIN is well suited for minimally invasive spine surgery offering a predefined, consistent and repeatable procedure,” said Didier Toubia, CEO, NLT SPINE. “Together with the PROW FUSION lumbar interbody fusion system, NLT SPINE offers a complete procedural solution. We are very pleased to announce that yet another NLT SPINE product has been cleared by the FDA, and our aim is to continue to develop innovative capabilities and technology that address complete procedural solutions for minimally invasive spine surgery.” The eSPIN system consists of a set of single use cutting tips, a hand-held instrument, a motor adaptor and a set of access and positioning instruments.

For more information about the company and technology please visit http://www.nlt-spine.com [1].

About NLT SPINE NLT SPINE specializes in the development of innovative Minimally Invasive Spinal Surgery (MISS) and percutaneous procedures for treating degenerative spinal conditions. The company’s vision is to improve patient care and reduce total treatment costs by shifting from traditional open surgical routines to MISS, 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.

CONTACT: NLT SPINE Tom Keegan, 508-272-7750 Vice President Business Development and US Marketing tom.k@nlt-spine.com [2] KEYWORD: UNITED STATES NORTH AMERICA NEW YORK MIDDLE EAST ISRAEL INDUSTRY KEYWORD: SURGERY HEALTH MEDICAL DEVICES FDA SOURCE: NLT SPINE Copyright Business Wire 2012 PUB: 09/20/2012 09:00 AM/DISC: 09/20/2012 09:00 AM http://www.businesswire.com/news/home/20120920005853/ [3]

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