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## **Simplify™ Cervical Artificial Disc Receives Two-Level IDE Approval**

### **Single-Level IDE Starting After NASS**

Sunnyvale, California, October 16, 2015 / PRNewswire / -- Simplify Medical, Inc. is pioneering disc arthroplasty with the non-metal, MRI compatible Simplify™ Disc, a cervical artificial disc. The Company announced today that it received Investigational Device Exemption (IDE) approval from the Food and Drug Administration (FDA) to initiate its two-level clinical trial comparing Simplify Disc with anterior cervical discectomy and fusion (ACDF) as a control. This approval allows the expansion of Simplify Medical's clinical operations.

The company plans to start its previously approved single-level study following the North American Spine Society (NASS) meeting currently being held in Chicago.

Simplify Disc is a cervical disc replacement composed of MRI compatible materials designed to eliminate invasive CT scans, reduce ionizing radiation exposure, and provide a metal-free option to patients. Simplify Disc offers disc heights as low as 4.1 mm for smaller patient anatomy.

The Simplify two-level IDE Trial is a prospective, multi-center, core lab adjudicated clinical trial evaluating the Simplify Disc at up to 14 clinical sites in the United States and Australia. The primary endpoint of the IDE trial is clinical success rate of Simplify Disc compared with ACDF.

David Hovda, CEO of Simplify Medical, said, "We have worked collaboratively with the FDA to achieve two-level IDE approval, and we look forward to starting this important study addressing a large segment of patients with cervical disc disease. We are excited to move forward with the Simplify Disc, which demonstrated promising clinical performance in an OUS clinical trial and commercial settings."

Simplify two-level IDE approval follows the recent Simplify single-level IDE approval and Simplify Disc CE Mark, allowing commercialization outside of the U.S. The company also announced it recently closed an investment by M.H. Carnegie, an Australian private equity/venture capital group. Mark Carnegie, Managing Director, commented, "Motion preservation provides patients with favorable clinical outcomes, and we believe Simplify Disc's MRI imaging capability can help reduce invasive CT scans and patients' exposure to ionizing radiation."

### **Simplify Cervical Disc**

The Simplify Disc is a cervical artificial disc composed of MRI compatible materials utilizing advanced polymers and ceramic, designed to eliminate the need for radiation-

intensive CT/Myelograms. The PEEK-on-ceramic articulation is designed for low levels of wear to optimize long-term durability, and Simplify Disc offers low height implant options for patients with smaller cervical disc spaces for whom larger implants are not optimal.

#### **About the Artificial Disc Market**

The *Journal of Orthopaedic Sports Physical Therapy* (2008;38(9):A1-A34) reports that 22-70% of the population will have neck pain at some point in their lives with chronic neck pain of greater than 6 months duration affecting 14% of individuals with neck pain. Neck pain is second only to low back pain in annual workers' compensation costs in the U.S.

#### **About Simplify Medical**

Simplify Medical is focused on cervical spinal disc arthroplasty, using innovative MRI friendly materials designed to decrease the need for ionizing radiation and enhance patient options. Simplify Medical is located in Sunnyvale, California. To learn more, visit our website at [www.simplifymedical.com](http://www.simplifymedical.com).

*Caution: the Simplify Disc is an Investigational device in the United States and is limited by law to investigational use.*