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## **Simplify™ Cervical Artificial Disc Receives IDE Approval**

**IDE approval follows recent CE Mark approval, with initial EU/Asia Pacific commercialization to begin in 2015**

Mountain View, California, March 16, 2015 / PRNewswire / -- Simplify Medical, Inc. is pioneering disc arthroplasty with the non-metal, MRI friendly Simplify™ 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 clinical trial comparing Simplify Disc with anterior cervical discectomy and fusion (ACDF) as a control. The Simplify IDE Trial is a prospective, multi-center, core lab adjudicated clinical trial evaluating the Simplify Disc at up to 10 U.S. sites.

Simplify Disc is a cervical disc replacement composed of MRI-friendly 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 4.2 mm for smaller patient anatomy.

David Hovda, CEO of Simplify Medical, said, "We have worked collaboratively with the FDA to achieve IDE approval, and we look forward to starting our study later this year. We are excited to move forward with the Simplify Disc, which demonstrated promising clinical performance in an OUS clinical trial and commercial settings."

IDE approval follows the recent Simplify Disc CE Mark, allowing international commercialization. The company also announced it was recently acquired by M.H. Carnegie, an Australian private equity/venture capital group. Mark Carnegie, Managing Director, commented, "We invested in Simplify Medical because we believe they have a better option for treating patients in a growing market in spine. We are working with the company to accomplish their mission of providing non-metallic, MRI-friendly, anatomically appropriate cervical artificial discs to patients worldwide."

### **Simplify Cervical Disc**

The Simplify Disc is an MRI compatible artificial disc composed of MRI friendly materials utilizing advanced polymers and ceramic, eliminating 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 anatomy.

### **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 Mountain View, 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.*