

## NEWS RELEASE



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For Immediate Release

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### **AxioMed Spine Corporation Receives CE Mark for Freedom® Lumbar Disc**

Garfield Heights, Ohio – May 12, 2009 – AxioMed® Spine Corporation ([www.axiomed.com](http://www.axiomed.com)) announces the receipt of CE Mark approval for its Freedom® Lumbar Disc, an elastomeric total spinal disc replacement device. The CE Mark approval was received from the notified body after review of the company's multi-center European clinical study and its portfolio of biocompatibility and biomechanical testing. This data also supported AxioMed's Investigational Device Exemption approval by the US Food and Drug Administration. The CE Mark clears AxioMed for the introduction of the Freedom® Lumbar Disc into the EU Market.

Patrick McBayer, AxioMed's President and CEO stated, "The Freedom® Lumbar Disc is the only elastomeric lumbar total disc replacement device to receive CE Mark approval based on a rigorous multi-center clinical study conducted in the European Union. We are particularly pleased to be able to provide surgeons in Europe with the Freedom technology that has been shown to provide patients pain relief, reduced disability and improved lifestyle, based on monitored outcomes and feedback. We are also active in our multi-center pivotal clinical study under an IDE for our Freedom® disc."

Neal Defibaugh, AxioMed's Vice President of Clinical and Regulatory Affairs, added, "Our European clinical study results, coupled with the extensive portfolio of biocompatibility and biomechanical testing, provided substantial information for our notified body to assess the Freedom® Lumbar Disc. This regulatory milestone and our US FDA Investigational Device Exemption approval demonstrate that the Freedom® Lumbar Disc's preclinical and clinical results can withstand rigorous regulatory review."

The Freedom® Lumbar Disc is a viscoelastic one-piece, next generation total disc replacement featuring a polymer core, designed with the goal of restoring function of the spine and reducing pain and disability. CE Mark approval allows for the commercial distribution of the Freedom® Lumbar Disc throughout the European Union. AxioMed's pivotal study, a multi-center US and EU evaluation of the Freedom® Lumbar Disc in skeletally mature patients with single-level

degenerative disc disease, is designed with efficacy, safety and economic endpoints. AxioMed is also developing a cervical total disc replacement which will follow a similar regulatory pathway.

### **About AxioMed Spine Corporation**

AxioMed's mission is to develop products focused on spinal function for patients with degenerative spine disease, thus advancing the standard of care beyond fusion and first generation discs. The Freedom Lumbar Disc was developed and designed by a team of clinicians and experts in the fields of biomechanics, pathology, spinal surgery and polymer science. Focusing on restoration of the natural function of the spine, AxioMed will enhance human health through research, innovation, development and service world-wide. For more information about AxioMed, please visit our web site at [www.axiomed.com](http://www.axiomed.com).