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Ortoviva Distractor Gains CE Certification

Ortoviva, a Swedish innovator of surgical instruments, has gained CE approval for their Distractor system, which improves and simplifies the insertion of disc prostheses in the spinal column. CE approval means that the entire European market is now open for the company.

Strong demand exists for truly effective instrument solutions that can help surgeons to simply and accurately implant an artificial disc without complications. The lack of proven instruments has limited the sphere of both suitable patients and surgeons. As a result, many people have been forced to continue suffering from back problems, and some may even undergo spinal-fusion procedures that are entirely unnecessary.

"Now we can provide a simple set of purpose-built instruments to facilitate deployment of disc prostheses and thus improve the probability for helping more patients return to a painless and normal life," says Ortoviva CEO, Stan Mikulowski.

From a functional perspective, the instruments in the Ortoviva Distractor solution hold and separate the two vertebrae adjacent to a damaged disc. This ability to mechanically control position and orientation enormously simplifies disc insertion.

"CE certification ensures that Ortoviva and the Distractor solution meet the most rigorous EU requirements. We're already seeing growing interest from clinical specialists as well as disc-implant manufacturers to start using the solution in this rapidly growing market. Before the end of the year we will begin live patient clinical trial programs and we plan to submit an application for FDA approval in the U.S. early in 2009," says Stan Mikulowski.

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Ortoviva develops instruments for spinal surgery that facilitate the deployment of artificial discs. The company was founded in October 2006 by LinkMed and a group of experts in bio-materials, spinal surgery and medical devices.
To see how Distractor works, go to: http://www.ortoviva.com/media/Distraktor.wmv

LinkMed works with visionary innovators to create new life-science companies. By adding skill and capital, LinkMed has built a portfolio of twelve companies: six in drug development and biotechnology, and six in medical technology. LinkMed is listed on the Stockholm Stock Exchange.

For additional information, please go to: www.ortoviva.com and www.linkmed.se

CE in brief
CE certification ensures that a product fully complies with EU safety regulations prior to being marketed in the European Union. CE certification plays an important role for free trade and harmonization of rules within the EU. Goods with the CE label are able to freely circulate in the EU internal Market.