

Media Release

## Synthes Receives FDA-Approval for ProDisc®-C

*West Chester, PA (USA), December 18, 2007*

**Synthes** (SWX: SYST.VX) is pleased to announce that the US FDA (Food and Drug Administration) has fully approved the **ProDisc®-C Total Disc Replacement** for commercial sale and distribution in the United States.

This decision follows the FDA's issuance of an Approvable Letter for ProDisc-C in October 2007 (see Media Release dated October 25, 2007). The clinical review had been completed at that time.

The remaining review of the associated manufacturing processes has now also been concluded and the FDA has determined that the respective requirements of the Quality System Regulations are fulfilled.

ProDisc-C has already been approved and used in Europe and other areas outside the US.

"We are very proud to be the first company to offer both a lumbar as well as a cervical artificial disc replacement on the US market; it will help to treat more patients with a physiological product in an important area of spinal disc degeneration. Furthermore, it will help Synthes to strengthen our market position in the segment of spinal motion preservation", says Michel Orsinger, President and CEO of Synthes.

Synthes will start with training of surgeons and a controlled roll-out of the product in January 2008.

The ProDisc-C Total Disc Replacement procedure is intended to significantly reduce pain caused by cervical disc degeneration. This is done by allowing for the removal of the diseased disc while restoring disc height and providing the potential for motion at the affected vertebral segment.

### **Synthes: A leading medical device company**

Synthes is a leading global medical device company. We develop, produce and market instruments, implants and biomaterials for the surgical fixation, correction and regeneration of the human skeleton and its soft tissues.

### **For further information please contact**

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