

Media Release

Synthes receives Approvable Letter from FDA for ProDisc™-C (cervical) Total Disc Replacement

Solothurn/Switzerland, October 25, 2007

Synthes announced today that it has received an Approvable Letter from the U.S. Food and Drug Administration (FDA) regarding the ProDisc™-C Total Disc Replacement. The Pre-Market Approval (PMA) request was submitted to the FDA in January 2007.

The letter means that the FDA has concluded its review of the ProDisc-C PMA and has determined that the device is safe and effective for use in replacing a diseased and/or degenerated intervertebral disc of the cervical spine in patients with symptomatic cervical disc disease (SCDD). The ProDisc-C Total Disc Replacement procedure is intended to significantly reduce pain by allowing for the removal of the diseased disc while restoring disc height and providing the potential for motion at the affected vertebral segment.

FDA has determined that the ProDisc-C is approvable subject to the satisfaction of applicable requirements of the Quality System Regulations (21 CFR Part 820).

FDA will issue an approval order after the manufacturing processes have been reviewed and determined to be acceptable. Commercial sale and distribution of the ProDisc-C Total Disc Replacement in the US may not begin until Synthes has received an approval order from FDA.

The FDA's decision included a review of the results of a human clinical trial of the ProDisc-C conducted over the course of three-and-a-half years. The study involved 209 patients at 13 clinical sites and compared ProDisc-C to Anterior Cervical Discectomy and Fusion (ACDF), which is the current standard of care.

Patients were evaluated for pain and disability, neurologic status and range of motion at the index level. Patients were followed for two years post surgery, and the data supports that ProDisc-C is a clinically proven alternative to cervical fusion.

ProDisc-C

The ProDisc-C Total Disc Replacement is a modular implant consisting of two CoCrMo (cobalt chromium molybdenum) endplates and one UHMWPE (Ultra High Molecular Weight Polyethylene) inlay. CoCrMo alloy was used in ProDisc-C Total Disc Replacement for its superior strength, proven biocompatibility, superior abrasion resistance, and superior wear characteristics when coupled with UHMWPE.

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.

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