K955884

SUMMARY OF SAFETY AND EFFECTIVENESS

NAME OF FIRM:	DePuy Inc. 700 Orthopaedic Drive Warsaw, Indiana 46581-0988
510(k) CONTACT:	Cheryl Hastings Manager, Pre-clinical Device Evaluation
TRADE NAME:	DePuy Coordinate II Revision Knee System
COMMON NAME:	Knee Prosthesis
CLASSIFICATION:	888.3560 - Prosthesis, knee, patellofemorotibial, semi-constrained, cemented, polymer/metal/polymer
DEVICE PRODUCT CODE:	87 JWH
SUBSTANTIALLY EQUIVALENT DEVICES:	▸ DePuy AMK Landmark Revision Knee System and Full Wedge Tibial Tray (renamed the Coordinate Revision Knee System) ▸ Johnson & Johnson P.F.C. Modular Knee System ▸ DePuy Synatomic Variable Fit Tibial Plateau ▸ DePuy AMK Congruency PS Tibial Inserts

INTENDED USE AND DEVICE DESCRIPTION:
The Coordinate II Revision Knee System is a design modification of the Coordinate Revision Knee System which was previously cleared by FDA for cemented use. The design modifications consist of the following: stem extensions for femoral and tibial components will be threaded rather than tapered; central posts on the femoral components and tibial trays will be modified to accept the threaded stem extensions; all tibial trays will be manufactured from cast Co-Cr-Mo; and the articular surface of the tibial inserts will be modified to be slightly more conforming.

The DePuy Coordinate II Revision Knee System is indicated for use with bone cement as either a primary or revision tricompartmental knee replacement system.

BASIS OF SUBSTANTIAL EQUIVALENCE:
The Coordinate II Revision Knee System is similar to the Coordinate Revision Knee System previously cleared by FDA with the exception of the design change listed under DEVICE DESCRIPTION.

The material, manufacturing process, intended use (cemented total knee arthroplasty) and the basic design of the Coordinate II Revision Knee System, including sizes of femoral components, tibial trays, and tibial inserts will not be changed from those of the Coordinate Revision Knee System previously cleared by FDA.

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