

JUN 18 1996

SUMMARY OF SAFETY AND EFFECTIVENESS

K961379

NAME OF FIRM: DePuy Inc.
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Warsaw, Indiana 46581-0988

FIRM CONTACT: Sally Foust
Clinical Research Specialist

TRADE NAME: DePuy AMK Porous Coated CRX Tibial Tray

COMMON NAME: Knee Prosthesis

CLASSIFICATION: 888.3560 Knee joint patellofemorotibial,
polymer/metal/polymer semi-constrained cemented
prosthesis

DEVICE PRODUCT CODE: 87 JWH

SUBSTANTIALLY EQUIVALENT DEVICES:
Depuy AMK Cemented CRX Tibial Tray
DePuy Synatomic Variable Fit Tibial Plateau
Howmedica PCA Modular Stemmed Tibial Baseplate

DEVICE DESCRIPTION AND INTENDED USE:

The DePuy AMK Porous Coated CRX Tibial Tray is a cast cobalt chrome tibial tray available in four standard sizes and five "plus" tibial sizes. The tray has a fixed, tapered, cylindrical central stem and two posterior fins originating at the central stem, and porous coating on the undersurface. The DePuy AMK Porous Coated CRX Tibial Tray is intended to be used as the tibial component in cemented total knee arthroplasty.

BASIS OF SUBSTANTIAL EQUIVALENCE:

The DePuy AMK Porous Coated CRX Tibial Tray is identical to the DePuy AMK Cemented CRX Tibial Tray cleared as the tibial component in cemented total knee arthroplasty except for the addition of the undersurface porous coating and the option of a tibial tray with screw holes.

Both the DePuy AMK Porous Coated and Cemented CRX Tibial Trays are manufactured from Co-Cr-Mo alloy and are available in four standard and five "plus" tibial sizes. Both have a fixed, tapered, cylindrical stem and two posterior fins originating at the central stem. The intended use (cemented total knee arthroplasty) of the AMK Porous Coated CRX Tibial Tray is identical to that of the DePuy AMK Cemented CRX Tibial Tray.

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