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OCT 1 1996

SUMMARY OF SAFETY AND EFFECTIVENESS

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

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Manager, Clinical Affairs

TRADE NAME: DePuy Graded Porosity AML Hip Prosthesis

COMMON NAME: Cemented or Cementless Porous Coated Hips

CLASSIFICATION: 888.3358 Hip joint metal/polymer semi-constrained porous coated uncemented prosthesis

DEVICE PRODUCT CODE: 87LPH

SUBSTANTIALLY EQUIVALENT DEVICES:

- ▶ DePuy 5/8 Porous Coated AML Hip Prosthesis
- ▶ DePuy Proximally Porous Coated AML
- ▶ DePuy Solution Hip Prosthesis

INTENDED USE AND DEVICE DESCRIPTION:

The Graded Porosity AML is indicated for uncemented or cemented use as the femoral component in total hip arthroplasty (THA) for replacing the hip joints of patients whose hip joint has been damaged by inflammatory or non-inflammatory degenerative joint disease, fracture or the failure of a previous arthroplasty.

It is a fully porous coated, cast Co-Cr-Mo femoral hip prosthesis available in four standard and four modified medial aspect (MMA) sizes. The porous coating consists of Co-Cr-Mo beads of various sizes. The stem is divided proximally/distally into five equal zones. A layer of the smallest beads is applied to the entire stem. A layer of the next larger beads is then applied to the most proximal 4 zones, a layer of the next larger beads is applied to the most proximal 3 zones etc. until the largest beads are applied as the outer layer of beads in the most proximal zone. The stem is sintered and HIPed once to attach all of the beads. The end result is a stem with 5 layers of different sized beads proximally, gradually reducing to 1 layer of the smallest beads distally.

BASIS OF SUBSTANTIAL EQUIVALENCE:

The Graded Porosity AML Hip is manufactured from the same material and has the same substrate geometry as the 5/8 Porous Coated and Proximally Porous Coated AML Hip Prostheses. The only difference between the Graded Porosity AML and the 5/8 and Proximally Porous Coated AMLs are that the Graded Porosity AML is a fully porous coated prosthesis and the porous coating is non-homogenous in bead size, pore size and porous coating thickness. The Graded Porosity AML is also similar to the Solution Hip Prosthesis in that both are fully porous coated and both are manufactured from the same material.

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