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SUMMARY OF SAFETY AND EFFECTIVENESS

NAME OF FIRM: DePuy Inc. MAR 27 1996
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TRADE NAME: DePuy Porocoat® HPS II Hip Prosthesis with
Articul-eze® Taper

COMMON NAME: Cemented or Cementless Porous Coated Hip

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

DEVICE PRODUCT CODE: 87LPH

**SUBSTANTIALLY
EQUIVALENT DEVICES:**

- ▶ Porocoat HPS II Hip Prosthesis
- ▶ DePuy Vision 5/8 Porocoat AML Hip Prosthesis
- ▶ DePuy Porocoat Prodigy Hip Prosthesis
- ▶ DePuy Apogee Hip Prosthesis with Porocoat

INTENDED USE AND DEVICE DESCRIPTION:

The Porocoat HPS II Hip Prosthesis with Articul-eze Taper is a design modification of the Porocoat HPS II Hip prosthesis which was previously cleared by FDA for cemented use. The design modification consists of changing the diameter of the taper and neck and adding the intended use of cementless fixation. In addition, five new stem sizes (one increased diameter and four reduced length stems) are being added.

The DePuy Porocoat HPS II Hip Prosthesis with Articul-eze taper is indicated for uncemented or cemented use as the femoral components in total hip arthroplasty 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.

BASIS OF SUBSTANTIAL EQUIVALENCE:

The subject Porocoat HPS II Prosthesis with Articul-eze taper is identical to the Porocoat HPS II Prosthesis previously cleared by FDA with the exception of the change in taper/neck design, the addition of a cementless use indication, and the addition of five new sizes. The Articul-eze taper design has previously been incorporated into the DePuy Vision AML Hip Prostheses, the Porocoat Prodigy Hip Prosthesis and the Apogee Hip Prosthesis with Porocoat. The material (ASTM F75 Co-Cr-Mo alloy), manufacturing process, intended use (with the exception of the additional indication of cementless use) and the basic design of the Porocoat HPS II Hip Prosthesis with Articul-eze taper have not changed from those of the Porocoat HPS II Hip Prostheses cleared by FDA in 1984.

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