

K961619

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

JUL 12 1996

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

510(K) CONTACT: Cheryl Hastings
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TRADE NAME: Endurance Calcar Hip Prosthesis

CLASSIFICATION: Hip prosthesis semi-constrained,
metal/polymer, cemented (21 CFR
888.3350)

DEVICE PRODUCT CODE: 87 JDI

**SUBSTANTIALLY
EQUIVALENT DEVICES:** DePuy Cemented Hip Stem
(tradenamed the Endurance Hip Stem)

DePuy AML Calcar Hip Prosthesis

DEVICE DESCRIPTION AND INTENDED USE:

The Endurance Calcar Hip Prosthesis is a forged Co-Cr-Mo stem, available in one size and two stem lengths. The design of the stem is similar to the design of the size 3 DePuy Cemented Hip Stem (now called the Endurance hip stem) except that the Endurance Calcar has an offset that is midway between the standard and high offset Endurance stems, does not have a collar and does have a 2.25cm calcar platform which is used to seat the implant.

The Endurance Calcar Hip Prosthesis is indicated for cemented use as the femoral component in total hip arthroplasty (THA) for replacing the hip joint of patients whose hip joint has been damaged by inflammatory or non-inflammatory degenerative joint disease, fracture or the failure of a previous arthroplasty. The stem is especially suited to primary or revision cases where the calcar of the femur may be deficient and for cases of intertrochanteric fracture.

BASIS OF SUBSTANTIAL EQUIVALENCE:

The Endurance Calcar Hip Stem is similar to the Endurance Hip Stem in that they have the same basic design, are manufactured from the same material and are both intended for use in cemented total hip arthroplasty. The Endurance Calcar Hip Stem is similar to the AML Calcar Hip Stem in that both stems have calcar platforms, are intended for use in cemented total hip arthroplasty, and can be used in cases where the calcar of the femur is deficient.

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