

K964704

SUMMARY OF SAFETY AND EFFECTIVENESS

JAN 24 1997

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

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TRADE NAME: DePuy/Ace MMA Fracture Stem

COMMON NAME: Cemented or Press-Fit Hip Stem

CLASSIFICATION: 888.3353 Hip joint, metal/ceramic/polymer,
semi-constrained, cemented or nonporous
uncemented prosthesis.

DEVICE PRODUCT CODE: 87 LZO

**SUBSTANTIALLY
EQUIVALENT DEVICES:** ♦ DePuy Vision AML Hip Prosthesis
♦ DePuy Quantum Hip Stem

DEVICE DESCRIPTION AND INTENDED USE:

The DePuy/Ace MMA Fracture Stem is a cast Co-Cr-Mo hip stem with a bead blasted finish. The stem has a triangular proximal body, a rounded shoulder, a straight distal stem, and anterior and posterior grooves that extend from the distal tip up approximately 60% of the length of the stem. Five sizes are available, ranging from 9 to 16.5mm in diameter. The DePuy/Ace MMA Fracture Stem has an Articul-eze (12/14) taper and is only to be used with the DePuy Co-Cr-Mo or Zirconia Articul-eze taper modular femoral heads (cleared in K883460 and K952088).

The DePuy/Ace MMA Fracture Stem is indicated for cemented or press-fit cementless use as the femoral component in total hip arthroplasty (THA) for replacing the hip joints of patients whose hip joint has been damaged by fracture. The prosthesis may also be used for total hip arthroplasty for patients requiring total hip replacement for inflammatory or non-inflammatory degenerative joint disease or failure of a previous arthroplasty.

BASIS OF SUBSTANTIAL EQUIVALENCE:

The DePuy/Ace MMA Fracture Stem is substantially equivalent to the DePuy Vision Modified Medial Aspect (MMA) AML Prosthesis in that both stems are manufactured from cast Co-Cr-Mo and both have the same basic geometry. The only differences in the designs of these two stems are that the Fracture Stem has distal anterior and posterior

DePuy/Ace MMA Fracture Stem and the DePuy Vision Standard Triangle AML have approximately the same fatigue strength. The DePuy/Ace MMA Fracture Stem is intended for cemented or press-fit cementless fixation. The DePuy Vision AML is intended for fixation either with cement or by tissue ingrowth into the porous coating. The DePuy/Ace MMA Fracture Stem is also substantially equivalent to the DePuy Quantum Hip Stem in that both are manufactured from cast Co-Cr-Mo and both have similar designs. The design differences between the Fracture Stem and the Quantum Stem are that the Fracture Stem has distal anterior and posterior grooves, a rounded rather than square lateral shoulder, and a reduced taper diameter and collar size compared to the Quantum Stem. The smallest Fracture Stem has a diameter of 9.0mm whereas the smallest Quantum Stem has a diameter of 10.5mm. Both the Fracture Stem and the Quantum Stem are intended for cemented or press-fit cementless fixation.