

K970503

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510(k) SUMMARY

NAME OF FIRM: DePuy ACE Medical Company
2260 East El Segundo Blvd.
El Segundo, CA 90245

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DePuy ACE Medical Company

TRADE NAME DePuy ACE Trochanteric Side Plate

COMMON NAME Bone Fixation Plate

CLASSIFICATION Single/Multiple Component Metallic Bone Fixation
Appliance and Accessories, 21 CFR 888.3030

DEVICE PRODUCT CODE 87 HRS Plate, Fixation, Bone

**SUBSTANTIALLY
EQUIVALENT DEVICE** DePuy ACE Captured Hip Screw Side Plate

INTENDED USE:

The DePuy ACE Trochanteric Side Plate is a side plate that is used in conjunction with the DePuy ACE Captured Hip Screw Assembly. The Trochanteric Side Plate is designed for use in osteotomies, arthrodeses, and hip fractures; including intertrochanteric, intracapsular, and subtrochanteric.

DEVICE DESCRIPTION AND SUBSTANTIAL EQUIVALENCE RATIONALES:

The DePuy ACE Trochanteric Side Plate is an optional component of the DePuy ACE Captured Hip Screw System (CHS). The new plate has a proximal extension with three holes placed in a triangular configuration. The proximal extension is designed for fixation of trochanteric fracture fragments. Hip fractures with comminution of the greater trochanter can be better controlled with use of the DePuy ACE Trochanteric Side Plate. By passing screws through the proximal flare, fixation of the greater trochanter and anti-rotation of the femoral head is controlled throughout the length of the plate. The DePuy ACE Trochanteric Side Plate is initially offered in 4, 6, and 8 hole configurations. The DePuy ACE Trochanteric Side Plate is manufactured from Ti-6Al-4V alloy.

The DePuy ACE Trochanteric Side Plate uses the same surgical technique for insertion as the DePuy ACE Captured Hip Screw Side Plate (which has been cleared to market by the FDA for hip fracture fixation since 1982). Both plates are manufactured from the same composition of Ti-6Al-4V; use the same Captured Hip Screw Assembly; are indicated for the same hip fractures; offer the same superior strength characteristics; are a low profile design; are inherently flexible allowing for plate conformity to the femur; and offer a proximal hole for use of 6.5mm screw.

Based on the above information, DePuy ACE Medical Company firmly believes that the new DePuy ACE Trochanteric Side Plate is substantially equivalent to the DePuy ACE Captured Hip Screw Side Plate.

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