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510(k) Summary

Proprietary Name: Alta® Dome and Plunger (MEC Hip Bolt)
Common Name: Hip Fracture Fixation Device
Classification Name: Single/Multiple Component Metallic Bone
Fixation Appliance and Accessories
888.3030

The Alta® Dome and Plunger, previously cleared by the FDA, is a titanium alloy device for the fixation of intracapsular and extracapsular (intertrochanteric) fractures of the hip. This submission adds an additional indication for the use of this device with bone cement. A small bolus of doughy bone cement is placed into the dome before it is mounted on the insertion tool. After insertion into the femur, the tool is tightened to extrude the cement into the surrounding cancellous bone. The addition of the bone cement provides enhanced early stability, reduced risk of superior cut-out and the ability to bear higher loads. The submission also describes several minor modification to the design of the device.

The substantial equivalence of this device is based on an equivalence to the previously cleared Alta® Dome and Plunger and to the use of other trauma devices for the fixation of femoral fractures with the augmentation of bone cement. Both the Howmedica Haig Nail and the Zimmer Haig Nail are indicated for use with bone cement in the stabilization of femoral fractures.

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