

K955871

510(k) Summary

Trade Name: Howmedica® Asymmetric Stem Femoral Component
Common Name: Femoral Hip Prosthesis
Classification Name: Hip Joint Metal/Polymer/Metal, Semi-Constrained, Porous Coated, Uncemented Prosthesis 888.3358

This device is a femoral component of a total hip system. Its substantial equivalence is based on an equivalence in labeling, design and materials to several legally marketed devices including: P.C.A.® E-Series Hip System (Howmedica); Straight Stem Femoral Component (Howmedica) and the Anatomic Hip (Zimmer).

All of the named devices are intended for use in the primary and secondary reconstruction of the head and neck portion of the femur. For the specific indication of primary non-inflammatory degenerative joint disease, the Howmedica® Asymmetric Stem Femoral Component is substantially equivalent to the P.C.A.® E-Series Hip and the Howmedica® Straight Stem Femoral Component. Relative indications and contraindications for use are the same for all of the named devices.

The Howmedica® Asymmetric Stem Femoral Component is manufactured from forged cobalt-chromium-molybdenum (Vitallium®) alloy which is similar to the material used in the P.C.A.® E-Series Hip and the Howmedica® Straight Stem Femoral Component.

Each of the named equivalent hip stems, as well as the Howmedica® Asymmetric Stem Femoral Component, share certain design features as follows: anatomic design (P.C.A. E-Series and Zimmer Anatomic Hips); circumferential porous coating (P.C.A.® E-Series Hip, Howmedica® Straight Stem Femoral Component and the Zimmer Anatomic Hip); collared and collarless versions (P.C.A.® E-Series Hip, Howmedica® Straight Stem Femoral Component and the Zimmer Anatomic Hip) and distal split (Howmedica® Straight Stem Femoral Component and the Zimmer Anatomic Hip).

Finite element analysis of this stem showed that the endurance load exceeds the Seimitsch minimum of 630 lbs.

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