

APR - 9 1997

510(k) Summary

Proprietary Name: Reliance® PF Femoral Stems

K970200

Common Name: Metallic Hip Stem

Classification Name and Reference: 21 CFR 888.3353
Hip Joint Metal/Ceramic/Polymer semi-constrained
cemented or nonporous uncemented prosthesis.

Proposed Regulatory Class: Class II
Device Product Code: LZO

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The Reliance® PF stem is a femoral component of a Total Hip System. It is intended to be used for primary or secondary reconstruction of the proximal femur damaged as a result of inflammatory, non-inflammatory, or traumatic joint disease. The Reliance® PF stem is intended to be used in conjunction with Howmedica's V40 femoral heads, Acetabular components, and unipolar and bipolar components. The stem can be press-fit into the proximal femur for fixation by mechanical interlock, or affixed with bone cement.

The Reliance® PF stem is manufactured from forged cobalt-chromium-molybdenum (Vitallium®) alloy.

The substantial equivalence of the Reliance® PF stem is based on an equivalence in intended use, materials, design, operational principles, and relative indications and contraindications to Howmedica's HNR Hip System (K903563), DRG Femoral component (K936126), Premium Femoral Component (K936127), and Dow Corning Wright's McCutchen Hip System.

Testing has demonstrated that the endurance load exceeds the Semlitsch minimum of 630 lbs.