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ORTHO DEVELOPMENT™

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Ortho Development Corporation 510(k) Summary

Proprietary Name: Primaloc™ Cemented Hip System

Common Name: Cemented hip prosthesis

Classification Name: Prosthesis, Hip, Hemi-,/Metal/Polymer Cemented

Regulatory Class: Class II

Intended Use

The Primaloc™ Cemented Hip System is intended for single, cemented use during primary or revision arthroplasty surgery. Indications include: (1) Osteoarthritis or rheumatoid arthritis, or other osteoarthroses of the hip joint; (2) Certain femoral neck fractures; (3) Idiopathic avascular necrosis; (4) Post traumatic arthritis; (5) Benign or malignant bone tumors where sufficient bone stock is present to seat the prosthesis; (6) Previously failed implant.

System Description

The Primaloc™ Cemented Hip is a straight tapered stem with a conical type collar at the base of the neck. The stem is made of Cobalt-Chromium Alloy (CoCr, ASTM F799), and the proximal cone incorporates macro grooves and a rough AlO_2 blasted surface for improved cement fixation. The femoral neck ends in a standard taper to interlock with Ortho Development Corporation Headloc™ CoCr modular femoral heads. A cement spacer, manufactured from PMMA, (polymethylmethacrylate, ASTM F451), is affixed to the proximal medial portion of the cone to help prevent varus insertion.
A distal centralizer, also made from PPMA, is affixed to the distal end of the femoral stem to align the stem within the medullary canal.
The Primaloc™ cement restrictor is manufactured from UHMWPE (ASTM F648). Prior to the introduction of bone cement into the medullary canal, the correctly sized cement restrictor is press-fit into the canal at a level below the final location of the implant. The cement restrictor incorporates annular grooves over its length to provide flexibility upon insertion.

Substantial Equivalence:

The Primaloc™ Cemented Hip System is a combination of state-of-the-art features and geometry; however, since it is similar to other cemented total hip systems currently in commercial distribution in terms of intended use, geometry, features, and materials, it is expected that its safety and effectiveness will be also be equivalent. The FDA cleared, commercially available cemented stems substantially equivalent to the Primaloc™ Cemented Hip System include:

Impact One-Piece Implant (Manufactured by Biomet)
S-ROM OPC I Hip Stem for Cement (Manufactured by Joint Medical Products)
Perfecta (Manufactured by Wright Medical, formerly Orthomet)

The Primaloc™ Cemented Hip System is substantially equivalent to the above-referenced hip systems for the following reasons: (1) the intended use for all referenced stems is identical to that of the Primaloc™ stem which is primary surgery in total hip arthroplasty (NINJD surgery or any of its composite diagnoses); (2) the referenced hip systems are all made from the same material, CoCr alloy, either cast of forged; (3) the dimensional characteristics regarding stem length and distal stem diameter are comparable; and (4) the referenced hip system geometry's are similar to the Primaloc™ in terms of design and features. While there are slight variances between the Primaloc™ and these referenced hip systems, there is no significant difference which would affect safety or efficacy.

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Date: June 21, 1996