

SEP 23 1996

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**510(K) Summary of  
Safety and Effectiveness**

**Submitter:** Orthopaedic Innovations, Inc.  
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**Date of Summary:** 07/01/96

**Product:** Classification Name: Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis, 21 CFR 888.3390  
Common Name: Modular Endo Head  
Trade/Proprietary Name: Prime Modular Endo Head

**Substantially Equivalent Products** Hemi-Head by Orthomet  
Modular Cathcart Endoprosthesis System by DePuy  
Unipolar Head by Smith and Nephew Richards

**Description** The Prime Modular Endo Heads feature a one piece spherical endo head and a Morse-type taper. This Morse-type taper provides for modular component selection, allowing the head to attach to the Prime Cemented Calcar Femoral Stems. The Prime Modular Endo Heads are provided in diameters from 36mm to 70mm in 1 mm (one millimeter) increments. It is constructed from Cobalt-Chrome Alloy, per ASTM F-1537. Sold Presterile.

**Intended Use:** The Prime Modular Endo Heads, with the Prime Cemented Femoral Stems, are intended to replace the femoral head in cases of femoral head and neck fracture, nonunion of femoral head and neck fractures, femoral head aseptic necrosis, osteoarthritis, rheumatoid arthritis and revision of failed hip fracture treatment.

**Comparison to Substantial Equivalent Products:** All made of the same types of materials, equivalent in function and design.