

K965164

MAR 13 1997

510(k) Summary

**Device: Howmedica® Modular Replacement System - Proximal Femur**

**The Howmedica® Modular Replacement System - Proximal Femur is presently cleared for use with bone cement in Oncology patients where radical resection and replacement of the proximal femur is required (reference premarket notification K952970). Howmedica seeks clearance to expand this indication to include use with bone cement in limb salvage procedures where radical resection and replacement of the proximal femur is required. Limb salvage procedures would include surgical intervention for severe trauma, failed previous hip arthroplasties, and/or Oncology indications. All of these surgical interventions have in common the need for radical resection of the proximal femur, and the need for a prosthetic replacement. This device achieves fixation by the use of bone cement.**

**A comparison to other legally marketed products was made, and testing of the modular tapers and fatigue testing of the proximal femur was presented.**

**For information contact:**

**Margaret F. Crowe  
Manager, Regulatory Affairs  
Howmedica Inc.  
359 Veterans Boulevard  
Rutherford, NJ 07070  
(201) 507-7431**