

## Summary of Safety and Effectiveness

Encore Orthopedics®, Inc.  
8900 Shoal Creek BLVD.  
Suite 300  
Austin, TX 78757  
512-206-1437  
Ashley M. Bock

K964008

DEC 27 1996

Trade Name: Femoral Component

Common Name: Femoral Component

Classification Name: Knee joint patellofemorotibial polymer/metal/polymer semiconstrained cemented prosthesis.

Description: This femoral component is available in six sizes, to fit into, and articulate with, the existing Foundation® Knee System. The CoCr alloy (ASTM F75) component is plasma sprayed with commercially pure titanium to provide a roughened surface to enhance fixation. The femoral component has two smooth pegs to provide medial/lateral stability.

Indications: The indications for use of this femoral insert are noninflammatory degenerative joint disease including osteoarthritis or traumatic arthritis, avascular necrosis of the femoral condyle, post-traumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy, moderate valgus, varus or flexion deformities, rheumatoid arthritis, treatment of fractures that are unmanageable using other techniques.

Comparable Features to Predicate Device(s): This device is similar in features, design and indications as the Foundation® Primary Knee System (K923277) and Biomet Maxim® Knee System.