



**WRIGHT**  
MEDICAL TECHNOLOGY, INC.  
5677 AIRLINE ROAD  
ARLINGTON, TN 38002  
901-867-9971

JAN 14 1997

## 510(k) Summary

K964249

**Contact Person:** Cliff Kline  
**Date Prepared:** September 23, 1996

**Trade/Proprietary Name:** BRIDGE™ Long Stem Femoral Component  
**Common Name:** Prosthesis, hip, semi-constrained, metal/ceramic/polymer/,  
cemented or non-porous, cemented  
**Product Classification:** Class II (888.3353)  
**Predicate Device:** The BRIDGE™ Hip System manufactured by Wright  
Medical Technology, Inc.

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92.

### Description/Intended Use

The BRIDGE™ Long Stem Femoral Component consists of two parts, a femoral stem designed with a primary mid-shaft metal seal and a polyethylene seal that provides a secondary seal at the mid-shaft region of the femoral stem. There are 20 sizes (ten right and ten left) for the BRIDGE™ Long Stem Femoral Component. This device is intended for cemented use only.

The BRIDGE™ Long Stem Femoral Component is indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

- 1) non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
- 2) inflammatory degenerative joint disease such as rheumatoid arthritis;
- 3) correction of functional deformity;
- 4) revision procedures where other treatments or devices have failed; and,
- 5) treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

### Testing

The BRIDGE® Long Stem Femoral Component demonstrates acceptable fatigue strength.