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Summary of Safety and Effectiveness
***Heritage*™ Hip Prosthesis System**

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- **Trade Name:**

  Heritage™ Hip Prosthesis System

- **Common Name:**

  Femoral Hip Prosthesis

- **Classification Name:**

  Hip Joint Metal/Polymer Semiconstrained Cemented Prosthesis, 21 CFR 888.3350

- **Predicate Devices:**

  Charnley-Type Total Hip Prosthesis
  ZCH Hip Prosthesis
  Longevity™ Monoblock Hip Prosthesis

- **Device Description:**

  The *Heritage* Hip Prosthesis is a modular cemented femoral hip prosthesis manufactured from forged high-strength *Zimaloy* Alloy. The design of the stem includes a small proximal collar with flats included on the anterior and posterior sides of the stem The medial surface of the stem is designed with a semispherical radius. The stems also have a distal hole for use with an optional distal centralizer. The angle of the stem neck is 132 degrees for greater offset and increased range of motion. The stem is designed with a Morse taper for use with modular femoral heads. The outer surface of the stems are smoothly polished for cemented use. Five primary stem sizes are available and described as sizes one through five. Two stems, CDH and valgus, are available with slightly less offset neck lengths as needed. Three revision stems are available.

- **Intended Use:**

  The *Heritage* Hip prosthesis is a single-use device intended for use in cemented total and hemi-hip arthroplasty procedures.

  The indications for total hip arthroplasty are:

  1. Patients suffering from severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head, and nonunion of previous fractures of the femur.

  2. Patients with congenital hip dysplasia, protrusio acetabuli, or slipped capital femoral epiphysis.

  3. Patients suffering from disability due to previous fusion.

  4. Patients with previously failed endoprostheses and/or total hip components in the affected extremity.

  5. Patients with acute femoral neck fractures.

  The indications for hemi-hip arthroplasty are:

  1. Fracture dislocation of the hip.

  2. Elderly, debilitated patients when a total hip replacement is contraindicated.

  3. Irreducible fractures in which adequate fixation cannot be obtained.

4. Certain high subcapital fractures and comminuted femoral fractures in the aged.

5. Nonunion of femoral neck fractures.

6. Secondary avascular necrosis of the femoral head.

7. Pathological fractures of the femoral neck.

8. Osteoarthritis in which the femoral head is primarily affected.

- **Performance Data:**

  Fatigue testing was performed on the proximal section of two stem sizes and on the distal section of another stem. All stems survived at the specified load for 10,000,000 cycles. The testing demonstrated that the stems met the predetermined design criteria and that the stems can be expected to perform similarly to other stems tested to the same criteria.

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