zimmer

OCT -8 1996

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Summary of Safety and Effectiveness
Delta Hip Prosthesis

- Submitted By:

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- Date:

  April 9, 1996

- Trade Name:

  Delta Hip Prosthesis

- Common Name:

  Femoral Hip Prosthesis

- Classification Name:

  Hip joint metal/polymer semiconstrained uncemented prosthesis

- Predicate Devices for the Femoral Stem:

  - AuFranc-Turner Type Total Hip, Charnley Type Total Hip, and Müller Type Total Hip, manufactured by Zimmer, preenactment devices

  - F-24 Femoral Hip Prosthesis, manufactured by Astel, K901687, cleared September 7, 1990

  - *TI-FIT*™ Total Hip System, manufactured by Smith & Nephew Richards, K873797, cleared November 2, 1987

- *Profile*™ Total Hip System, manufactured by DePuy, K850055, cleared April 23, 1985

- CLS Total Hip Replacement System (Protek, Inc.), distributed by Intermedics Orthopedics, Inc.

• Device Description

The Delta Hip Prosthesis is a collarless, modular femoral stem manufactured from either *Tivanium* or Ti-6Al-7Nb alloy both of which are high-fatigue strength materials with a history of successful clinical use and exceptional biocompatibility. Delta Hip stem sizes 9 through 15, 17 and 19 will be available in either material.

The Delta Hip Prosthesis is designed for primary hip replacement in patients with a champagne flute type femur. The trapezoidal geometry provides for maximum metaphyseal fill of the proximal femur and apposition to cortical bone. Rotational stability is enhanced by the wedge fit of the stem in the proximal femur.

The modular connection of the femoral stem is a Morse-type 12/14 neck taper designed to mate with the corresponding 12/14 bore of a femoral head component.

• Intended Use

The Delta Hip Prosthesis is designed for press-fit fixation into the human femur as a component in either total hip or hemi-hip replacement and is indicated for the following:

- Total Hip Replacement

  Severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head, nonunion of previous fractures of the femur; congenital hip dysplasia, protrusio acetabuli, slipped capital femoral epiphysis; disability due to previous fusion; previously failed endoprostheses, and acute femoral neck fractures.

- Hemi-Hip Replacement

  Fracture dislocation of the hip; elderly, debilitated patients when a total hip replacement is contraindicated; irreducible fractures in which adequate fixation cannot be obtained; certain high subcapital fractures and comminuted femoral neck fractures in the aged; nonunion of femoral neck fractures; secondary avascular necrosis of the femoral head; pathological

fractures of the femoral neck; and osteoarthritis in which the femoral head is primarily affected.

- Comparison to Predicate Devices

The Delta Hip Prosthesis is substantially equivalent to all hip systems listed above in that each is intended for cementless fixation into the intramedullary canal for pathological or degenerative conditions involving the femur and/or acetabulum. All predicate devices are manufactured from metal alloys that have a history of successful clinical use in orthopaedic applications.

- Clinical and Nonclinical Data

A current method of hip prosthesis implantation relies on mechanical fixation through initial implant stabilization with secondary fixation supplied by bone ongrowth. The Delta Hip Prosthesis is an example of a device designed to achieve biologic fixation to bone without the use of bone cement.

Many studies published in the literature report satisfactory results with the use of hip prostheses that are substantially equivalent to the Delta Hip Prosthesis.

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