



zimmer

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**Summary of Safety and Effectiveness
Zimmer® Zirconia Ceramic Femoral Head**

- Submitted by:

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- Prepared by:

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- Trade Name:

Zimmer® Zirconia Ceramic Femoral Head

- Classification Name:

Hip joint metal/ceramic/polymer semiconstrained cemented or nonporous uncemented prosthesis, 21 CFR 888.3353

- Predicate Devices:

- *Zimmer® Zirconia Ceramic Femoral Heads, 22 through 28 mm*

- Device Description:

The *Zimmer Zirconia Ceramic Femoral Head* is made from yttria stabilized zirconia oxide (ZrO₂) ceramic and provides an alternative to cobalt-chrome alloy, and aluminum oxide ceramic femoral heads. The *Zimmer Zirconia Ceramic Femoral Head* is intended for mating with either a *Tivanium® Ti-6Al-4V Alloy* or *Zimaloy® Cobalt-Chrome-Molybdenum Alloy* modular femoral stem equipped with a tapered neck of identical dimensions. The *Zimmer Zirconia Ceramic*

Femoral Head is designed to articulate upon the UHMWPE-bearing surface of an acetabular component.

The prosthesis is supplied in 22, 26, and 28 mm diameters and a variety of neck lengths.

- Intended Use:

The *Zimmer Zirconia Ceramic Femoral Head* is designed to be implanted into the human hip as a component in total hip arthroplasty and is indicated for the following:

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; patients with congenital hip dysplasia, protrusio acetabuli, or slipped capital femoral epiphysis; patients suffering from disability due to previous fusion; patients with previously failed endoprotheses and/or total hip components in the operative extremity; and patients with acute neck fractures.

- Comparison to Predicate Devices:

The *Zimmer Zirconia Ceramic Femoral Head* is substantially equivalent to the femoral heads listed above as predicate devices. Each is designed to function as the modular femoral head component of a total hip prosthesis, is impacted onto the proximal taper of a femoral stem at the time of surgery, and articulates upon the UHMWPE-bearing surface of an acetabular component.

The *Zimmer Zirconia Ceramic Femoral Head* and the *Zimmer Femoral Head* for tapered neck provide the same size range (22, 26, and 28 mm diameters) and support the same type of taper for impaction upon the femoral stem component. The *Zimmer Zirconia Ceramic Femoral Head* and the *Zimmer Ceramic Femoral Head* (28 and 32 mm diameters) provide a 28 mm diameter head component, support the same type of taper for impaction upon the femoral stem component, and are made from ceramic materials. The *Zimmer Zirconia Ceramic Femoral Head* and the Richards and Biomet Zirconia Ceramic Femoral Heads provide similar size ranges and support similar tapers for impaction upon the femoral stem component. The material from which they are made is the same: zirconium oxide ceramic.

- Clinical and Nonclinical Data

Ceramic materials have been successfully used in orthopaedic applications for

approximately 20 years. These materials exhibit excellent resistance to corrosion and wear and are highly biocompatible. The yttria stabilized zirconium oxide from which the *Zimmer Zirconia Ceramic Head* is made has limited clinical history. Although mechanical testing demonstrates that when used with polyethylene acetabular cups, the zirconia ceramic femoral head produces a relatively low amount of particulates, the total amount of particulate produced remains undetermined. Because of limited clinical and preclinical experience, the long-term biological effects of these particulates are unknown. Clinical investigation of the zirconium oxide ceramic prosthesis is ongoing.

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