

K964150

510(k) Statement

DEC 27 1996

Device:

Classification Name:	prosthesis, hip semiconstrained,metal, polymer, porous, uncemented
Classification No.:	87LZO
Common/Usual Name:	zirconia ceramic femoral head
Proprietary Name:	Whiteside Biomechanics Zirconia Ceramic Femoral Head

Manufacturer Identification:

Whiteside Biomechanics, Inc.
12634 Olive Blvd.
Creve Coeur, MO 63141

Establishment Registration Number: 1932213

Device Description:

The Whiteside Biomechanics Zirconia Ceramic Femoral Head will consist of a generally spherical, partially hollow (trunnion bore) ceramic ball. The implant will have a machined flat on the most distal surface with the trunnion centered and machined proximally into its center. The bore will be a Whiteside Biomechanics 12/14 taper intended to be seated on a trunnion compatible with this taper (see warning label). The head outer perimeter is intended to articulate with a polyethylene acetabular component of compatible size. Labeling on the femoral head will be printed on a beveled surface machined around the periphery of the trunnion bore.

Intended Use:

This device is intended to be used for:

1. noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis,
2. rheumatoid arthritis,
3. correction of functional deformity,
4. revision procedures where other treatments or devices have failed,
5. treatment of non-unions, femoral neck and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques,
6. treatment/reduce pain,
7. treatment of osteomyelitis,
8. endoprosthesis femoral osteotomy,
9. use determined by the physician using sound medical judgment.

Additional Information:

This femoral head is made from magnesia stabilized zirconia ceramic. The device is to be sterilized with 100% ethylene oxide in nitrogen according to the AAMI guidelines for sterilization. Resterilization of femoral heads upon contamination is not recommended. DO NOT RESTERILIZE.