

SEP 10 1996

K961625

510(k) SUMMARY

Device:

Classification Name:	Prosthesis Hip, Semi-constrained, Metal / Polymer, Porous Uncemented
Classification No.:	87LPH
Common / Usual Name:	Modular femoral component and head
Proprietary Name:	Quatroloc Femoral Component and Head

Manufacturer Identification:

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

Establishment Registration Number: 1932213

Device Description:

The implant will consist of a solid, rectangularly cross-sectioned wrought titanium 6Al-4V (ASTM 1472) stem with a tapered proximal end intended to seat a conventional cobalt-chrome modular spheric articular interface. The device is intended to articulate with a conventional acetabular implant of the surgeon's choice. The distal will be a smooth taper A-P and will be step-cut with parallel sides M-L. The proximal stem will be porous coated with commercially pure titanium beads on all surfaces excluding the articular interface trunnion.

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, and
5. treatment of non-unions, femoral neck and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.

Additional Information:

This femoral component is made of wrought titanium 6Al-4V (ASTM F1472). The proximal portion of the stem will be porous coated on all surfaces, excluding the ball trunnion. The porous coating will consist of 3 layers (0.030" total thickness) of commercially pure titanium beads (-45+60Mesh). The device is to be sterilized with 100% ethylene oxide and nitrogen in accordance with AAMI guidelines for sterilization.