K96 3998

Summary of Safety and Effectiveness

Encore Orthopedics®, Inc.
8900 Shoal Creek Blvd.
Suite 300
Austin, TX 78759
(512) 206-1437
Ashley M. Bock

JAN 2 7 1997

Trade Name: Metal Backed Acetabular Component

Common Name: Metal backed acetabular component

Classification Name: Hip joint metal/polymer semi-constrained uncemented prosthesis per 21 CFR 888.3358

Description: The metal shell is fabricated from wrought/forged or cast Ti-6Al-4V. The outside surface of the shell is plasma sprayed to provide a roughened surface for enhanced press-fit fixation.

The metal shell is hemispherical in shape and is available with screw holes. The screw holes are for the use of cancellous bone screws for secondary fixation.

The poly liners are manufactured from ultra high molecular weight polyethylene and are available in a neutral and 10° hooded design. The hooded design is intended for those patients prone to subluxation because of soft tissue laxity.

Intended Use: The metal backed acetabular component is intended for treatment of patients who are candidates for total hip arthroplasty because the natural femoral head and neck and/or acetabulum have been affected by osteoarthritis, inflammatory arthritis, traumatic arthritis, rheumatoid arthritis, avascular necrosis or femoral neck fracture, and revision arthroplasty where bone loss is minimal. These devices are intended to aid the surgeon in relieving the patient of hip pain and restoring hip motion.

Comparable Features to Predicate Device(s): The spherical shape, titanium substrate, indexability of liners in shell and bone screw holes are features that are comparable to other devices in commercial distribution. The outside surface of the shell is plasma sprayed to provide a roughened surface for enhanced fixation. The Encore® metal backed acetabular component flares at the rim to enhance the press-fit fixation, with a straight line rather than a change in radius .

Test Results: Testing on this device included attachment strength of liners to shell. All results are sufficient for *in-vivo* loading.