BIOMET INC®

K970501 APR 30 1997

Summary of Safety and Effectiveness

Sponsor: Biomet, Inc.
Airport Industrial Park
Warsaw, Indiana 46580

Device Name: Pegged Acetabular Component

Classification Name: Hip joint metal/polymer/metal semi-constrained porous coated uncemented prosthesis (888.3358) and Hip joint metal/polymer semi-constrained cemented prosthesis (888.3350)

Device Description: The Pegged Acetabular Component is a full hemispherical metallic shell. The shell has three superiorly places pegs or spikes to provide initial fixation and rotational control. The outer surface of the shell is porous coated. The device is to be used in conjunction with Biomet's Ringloc Acetabular Liners. The device may be used in conjunction with any commercially available femoral component.

Intended Use: The Pegged Acetabular Component is intended for use in reconstruction of the hip joint due to disease, deformity of trauma. The device is intended for cemented application for general use and non-cemented application in skeletally mature individuals undergoing primary surgery for rehabilitating hip joints damaged as a result of non-inflammatory degenerative joint disease or any of its composite diagnoses. The device is a single use implant.

Potential Risks: The potential risks associated with this device are the same as with any joint replacement device. These include, but are not limited to:

Reaction to the bone cement	Blood vessel damage	Bone fracture
Deformity of the joint	Soft tissue imbalance	Infection
Cardiovascular disorders	Delayed wound healing	Hematoma
Fracture of the cement	Metal sensitivity	Dislocation
Implant loosening/migration	Fracture of component	Excessive wear
Breakdown of porous surface	Tissue growth failure	Nerve damage

Substantial Equivalence: The Pegged Acetabular Component is substantially equivalent to almost all acetabular devices on the market in overall design and intended function. Predicate devices include:

Universal® Acetabular Component (Biomet)
Mallory-Head® Acetabular Component (Biomet)
Reflection™ Porous-Coated Acetabular Component (Richards)
PCA® Acetabular Component (Howmedica)
Duraloc™ 300 Acetabular Cup System (DePuy)