BIOMET INC®

CORPORATE HEADQUARTERS

K961260

APR -2 1997

Summary of Safety and Effectiveness

Sponsor: Biomet, Inc.
Airport Industrial Park
P.O. Box 587
Warsaw, IN 46581-0578

Device: Kirschner Shoulders with Titanium Plasma Spray

Classification Name: Prosthesis, shoulder, non-constrained, metal/polymer cemented and Prosthesis, shoulder, humeral (hemi-shoulder) metallic

Indications for Use: 1) Relief of severe pain or significant disability in degenerative, rheumatoid, or traumatic disease of the glenohumeral joint. 2) Irreducible 3 and 4 part fractures of the proximal humerus. 3) Non-united or mal-united chronic humeral head fractures or fracture-dislocations. 4) Avascular necrosis of the humeral head. 5) Other difficult clinical management problems, including failed reconstructive procedures, where arthrodesis of resection arthroplasty are not considered acceptable.

Device Description: The Kirschner Shoulders are all based on the original design concept of the Neer Shoulder. Common design features include Cobalt-Chromium-Molybdenum alloy substrate; smooth, distally tapered stem; grooves in the stem to aid in cement pressurization and provided torsional stability; four proximal fins to provided rotational stability and facilitate positioning during insertion; continuous radius of curvature humeral head geometry and; all humeral heads are compatible with all glenoid components. Kirschner II-C Humeral Stems are one piece in that the head and stem are an single component. Modular II-C Humeral Stems are a one piece stem with a modular head attached by a Morse-type taper. Atlas-C Modular Stems are two piece stems composed of a proximal humeral component and a distal stem attached by a screw thread. This component also utilizes a modular humeral head. The Modular Glenoid Metal Backing provides reinforcement to a polyethylene bearing surface. The design is identical to the predicate device.

This 510(k) is for a change from a cobalt alloy plasma spray coating to a titanium alloy coating and a change in the manufacturing location. All other aspects of the device remain the same.

MAILING ADDRESS
P.O. Box 587
Warsaw, IN 46581-0587

SHIPPING ADDRESS
Airport Industrial Park
Warsaw, IN 46580

OFFICE
219.267.6639

FAX
219.267.8137

E-MAIL
biomet@biomet.com

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 the components	Excessive wear
Nerve damage	Disassociation of the modular head	

Substantial Equivalence: In function and overall design, the Kirschner Shoulders with Titanium Plasma Spray are equivalent to almost all hip components on the market.

Devices are identical to the following predicate Kirschner products:

- Kirschner II-C Humeral Stems - K873073
- Modular II-C Humeral Stems - K874643
- Atlas-C Modular Proximal Humeral Components - K940537
- Modular Glenoid Metal Backing - K873104