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Summary of Safety and Effectiveness

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

Device: Kirschner® Knee Modified

Classification Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis (CFR 888.3560).

Indications For Use: Total knee replacement is indicated for patients suffering from severe knee pain and disability. Specific indications include femoral, tibial and patellar replacement in a wide size range of patients who require implantation due to degenerative bone disease such as rheumatoid arthritis or osteoarthritis, primary and secondary traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral condyle, pseudo-gout or complications from a failed prosthesis.

Device Description: The Kirschner® Knee Modified encompasses the Kirschner Performance Total Knee System, Kirschner TC-IV Total Condylar Knee System and Kirschner HybridFit Total Knee.

Kirschner Performance Total Knee System features an anatomically designed cast cobalt chromium femoral component whose geometry allows for maximum range of motion and size interchangeability. It comes with a non-porous coated proximal supracondylar flange and two non-porous coated fixation pegs to minimize stress shielding and permit compression between the porous coated surface and bone. Five sizes in left/right anatomic configurations are available to better match the patient's anatomy. The modular titanium tibial component has four screw holes and comes with either a cruciate or round stem. Available is an all poly tibial component. There are femoral and tibial augmentations to fill cavitary defects.

Kirschner TC-IV Total Condylar Knee System features a cobalt chromium femoral component with a "waffled" non-porous coated proximal flange and two non-porous fixation pegs. The one-piece cobalt chromium tibial component has a posterior recess allowing for the retention of the posterior cruciate ligament.

The UHMWPE patellar component for both the Performance and TC-IV knee systems come in porous-coated metal-backed or all UHMWPE options.

The HybridFit cobalt chrome tibial tray accepts the TC-IV or Performance bearing inserts and can be used with either the Performance or the TC-IV femoral component.

These knee devices are intended for use with bone cement.

The major changes are in material and method of the porous coating and in the manufacturing process of the Ultra High Molecular Weight Polyethylene.

Porous coated Kirschner Knees Modified features Biomet's plasma spray coating of titanium alloy powder. The integrity of this coating has been proven in the performance of many Biomet joint prosthesis previously reviewed by the FDA. There have been no reported incidents of coating failure.

The polyethylene components are of ArCom UHMWPE, Biomet's improved polyethylene components.

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 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	Tissue growth failure	Excessive wear
Fracture of the components	Nerve damage	

Substantial Equivalence: In function and overall design, Biomet's Kirschner Knee Modified knee components are equivalent to almost any knee components on the market, including:

Maxim Total Knee System (Biomet, Inc.) 510(k)# K915132 cleared for market 2/11/92.

AGC 2000 Total Knee Prosthesis (Biomet, Inc.) 510(k)# K833921 cleared for market 1/31/84.