

Summary of Safety and Effectiveness

Sponsor: Biomet, Inc.
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KL 943025

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Device: Freeman/Samuelson Total Knee System

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

Device Description: The Freeman/Samuelson Knee is a Co-Cr-Mo femoral component, a Co-Cr-Mo backed polyethylene tibial component and a polyethylene patellar component designed to replace a damaged or disease knee joint. Indications include the relief of pain and restoration of motion due to non-inflammatory degenerative joint diseases, rheumatoid arthritis, deformities of the knee and revisions of previously failed knee replacements. The device is intended for use with bone cement.

The system features interchangeability between all sizes of components. The femoral component is available with or without a central stem and offers the option of using finned polyethylene pegs or splined titanium pegs for added fixation of the femoral component. The tibial component has a central stem and attached splined pegs. The polyethylene bearing surface is molded to the metal tibial base plate. The all polyethylene patella component has a finned fixation peg. The patella is contoured to provide greater surface contact than traditional domed patellar 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:

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|-----------------------------|----------------------------|----------------|
| 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 |
| Tissue growth failure | Nerve damage | |

Substantial Equivalence: In function and overall design, Biomet's Freeman/Samuelson Total Knee System is equivalent to almost all knee components on the market. These stems include:

- AGC 2000 Total Knee Prosthesis (Biomet, Inc., Warsaw, IN)
- Maxim Knee System (Biomet, Inc., Warsaw, IN)
- Freeman/Samuelson Total Knee (Depuy, Warsaw, IN)
- Freeman/Samuelson Mark II Press-fit (Protek, Indianapolis, IN)
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