K962137

**Summary of Safety and Effectiveness**
**Smith & Nephew Richards Inc.**
**Genesis II Constrained System**

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## Substantial Equivalence Information

The Genesis II Constrained System is similar to the following knee systems

1. Genesis Constrained Knee System - Smith & Nephew Richards
2. Genesis II Knee System - Smith & Nephew Richards
3. Genesis I P/S Knee Systems - Smith & Nephew Richards
4. Insall/Burstein Constrained Condylar Knee - Zimmer
5. P.F.C. Modular Knee System - Johnson & Johnson
6. Omnifit Total Knee System - Osteonics
7. Coordinate Revision Knee System - Depuy

All of the devices listed above are similar in design to the Genesis II Constrained System. The safety and effectiveness of the Genesis II Constrained System is based on the long history of use of these devices in the market place.

## Device Description

The Genesis II Constrained System consists of a femoral component and a tibial insert. The femoral component is manufactured from cobalt-chromium-molybdenum and the tibial insert is manufactured from ultra-high-molecular-weight polyethylene. The femoral component has a box-like design that mates with a post on the tibial insert to constrain motion.

## Indications for Use

The Genesis II Constrained System is indicated for:

1. Rheumatoid arthritis.
2. Post-traumatic arthritis, osteoarthritis, or degenerative arthritis in older patients whose age, weight, and activity level are compatible with an adequate long-term result.
3. Failed osteotomies, unicompartmental replacement, or total knee replacement.
4. The Genesis II Constrained System is designed for use in patients in primary and revision surgery, where the posterior cruciate ligament and one or both of the collateral ligaments (i.e. medial collateral and/or lateral collateral ligament) are absent or incompetent.

The Genesis II Constrained System is indicated for use with cement and is a single use device.

## Mechanical Testing

Mechanical testing was performed according to the requirements in the knee draft guidance document. All of the test results indicate that the Genesis II Constrained System is capable of withstanding *in vivo* loading without failure.