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Summary of Safety and Effectiveness

Smith & Nephew Orthopaedics

Genesis II Zirconium Femoral Component

Profix Zirconium Femoral Component

Substantial Equivalent Information

The Genesis II Zirconium Femoral Component and the Profix Zirconium Femoral Component are similar to the devices listed below.

1. Genesis II C/R and LDK Femoral Component
2. Profix C/R Femoral Component
3. Genesis I C/R Femoral Component

The devices listed above are similar in design to the Genesis II Zirconium Femoral Component and the Profix Zirconium Femoral Component. The zirconium alloy material used to manufacture the Genesis II Zirconium Femoral Component and the Profix Zirconium Femoral Component is the same material used for both the Zirconium Alloy Femoral Head and the Zirconium Alloy Uni-Polar Head.

Device Description

The Genesis II Zirconium Femoral Component and the Profix Zirconium Femoral Component are cruciate retaining components indicated for use with existing Genesis II and Profix System Components. Both are manufactured in a variety of sizes in both left and right orientations.

Indications for Use

Genesis II and Profix Knee Systems are 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.

Genesis II and Profix Knee Systems are indicated for use only with cement and are single use devices.

Preclinical Testing

Mechanical testing was performed according to the requirements in the knee draft guidance document. Testing was also performed to characterize the material properties. All of the test results indicate that both the Genesis II Zirconium Femoral Component and the Profix Zirconium Femoral Component are capable of withstanding *in vivo* loading without failure.