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Summary of Safety and Effectiveness
***NexGen®* Complete Knee Solution Legacy Posterior Stabilized (PS) and**
Constrained Condylar Knee (CCK) Femoral Components and Articular Surfaces

Information is being submitted in accordance
with the requirements of SMDA 1990

APR 26 1996

- Submitted by:

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- Prepared by:

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Regulatory Affairs Associate

- Date:

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- Trade Name:

NexGen Legacy PS (L-PS) and *NexGen* Legacy CCK (L-CCK)

- Classification Name:

Knee joint femorotibial metal/polymer semiconstrained cemented prosthesis

- Predicate Devices:

- ▶ The *NexGen* Legacy Posterior Stabilized Knee equals *NexGen* Posterior Stabilized and *Insall/Burstein* II Posterior Stabilized
- ▶ The *NexGen* Legacy Constrained Condylar Knee equals *NexGen* Constrained Condylar Knee, *Insall/Burstein®* II Modular Knee System, and *Insall/Burstein®* Constrained Condylar Knee

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- Intended Use:

To reduce or relieve pain and restore function and motion to the knee joint. Total knee replacement is indicated for patients with severe knee pain and disability due to rheumatoid arthritis, osteoarthritis, primary and secondary traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral condyle or pseudogout, posttraumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy, moderate valgus varus or flexion deformities.

- Comparison to Predicate Devices:

See attached chart.

- Clinical and Nonclinical Uses:

Current methods of implant fixation rely on the use of bone cement. Numerous studies reported in literature indicate satisfactory results have been obtained through use of devices to which substantial equivalence is claimed.

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