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P.O. Box 708
Warsaw, IN 46581-0708
219 267-6131

Summary of Safety and Effectiveness
NexGen™ Complete Knee Solution, 9 mm Tibial Articular Surfaces

This 510(k) Summary of Safety and Effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act of 1990.

- Submitted by:

Zimmer, Inc.
345 East Main Street
P.O. Box 708
Warsaw, Indiana 46581-0708

- Prepared by:

Ruth Ann Wood
Regulatory Affairs Associate

- Date:

March 15, 1995

- Trade Name:

NexGen™ Total Knee Solution
9 mm Tibial Articular Surface

- Classification Name:

Knee joint patellofemorotibial polyethylene/metal/polyethylene semiconstrained cemented prosthesis 21 CFR 888.3560.

- Identification of the Predicate Device:

MG II® Total Knee System and Insall/Burstein® II Modular Knee System

- Summary Description:

The NexGen™ Complete Knee Solution, 9 mm articular surfaces are made of molded ultra-high molecular-weight polyethylene (UHMWPE). As with the MG II Knee, each



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articular surface is snapped into one of a series of the *NexGen* Knee tibial plates. The components are curved in both the frontal and sagittal planes. The posterior stabilized version having slightly more curvature in the anterior portion of the sagittal plane.

- Summary of Intended Uses:

The device is intended to reduce or relieve pain and restore function and motion to the knee joint.

- Comparison to the Predicate Device:

The 9 mm tibial articular surfaces have the same basic geometric shape, intended use and material as the predicate device.

- Clinical and Nonclinical Data:

Numerous studies reported in the literature for the predicate devices indicate that satisfactory results have been obtained through the use of 9 mm tibial articular surfaces.

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