zimmer

AUG 23 1996

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K962196

Summary of Safety and Effectiveness

The summary of safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990.

- Submitted by:

  Zimmer, Inc.
  P.O. Box 708
  Warsaw, IN 46581-0708

- Prepared by:

  Ruth Ann Wood
  Senior Regulatory Affairs Associate

- Date:

  June 5, 1996

- Trade Name:

  NexGen® Complete Knee Solution with *Co-Nidium*™ Surface Hardening Process and *Legacy*™ Knee System with *Co-Nidium*™ Surface Hardening Process

- Classification:

  Class II
  21 CFR 888.3530

- Predicate Devices:

  Cobalt-Chromium Molybdenum Alloy Femoral Heads with *Co-Nidium* Surface Hardening Process; *MG II*® Total Knee System with *Ti-Nidium*® Surface Hardening Process; *MG* II® Porous Total Knee System, *NexGen*® Complete Knee Solution; and the *Legacy*™ Knee System

- Device Description:

  The femorals are made of cast *Zimaloy*® Cobalt-Chromium-Molybdenum Alloy. They are hardened by the *Co-Nidium*™ Surface Hardening Process described in

They are hardened by the *Co-Nidium*™ Surface Hardening Process described in Section XI. They are available in left and right configurations. *NexGen/Legacy* Knee femorals cover a multitude of patient specific needs with the Cruciate Retaining (CR), Posterior Stabilizing (PS and L-PS), Cruciate Retaining Augmentable (CRA), and Constrained Condylar Knee (L-CCK) designs. Certain femorals can be augmented with stem extensions. The extensions come in a broad variety of straight and offset shapes as well as numerous lengths and diameters. These femorals will be available in precoat, porous, and option (NoCoat) versions.

- Intended Use:

  Knee femoral components are single use devices implanted in the human knee during total knee arthroplasty. This knee is intended for cement use only.

- Performance Data:

  The performance data submitted in the 510(k) demonstrated the improved wear resistance compared to nontreated femoral components.

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