



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

K963148

**Summary of Safety and Effectiveness**

**FEB 13 1997**

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, Indiana 46581-0708

- Prepared by:

Ruth Ann Wood  
Senior Regulatory Affairs Associate

- Date:

August 12, 1996

- Trade Name:

*NexGen*® Complete Knee Solution Fluted Stemmed Tibial Component

- Classification:

Class II  
21 CFR 888.3530

- Predicate Devices:

*NexGen*® Complete Knee Solution and the *Insall/Burstein*® Total Knee System

- Device Description:

The proposed fluted, stemmed tibials are made of forged *Titanium*® Ti-6Al-4V Alloy. Like the tibials, *NexGen*® Complete Knee Solution, the fluted stemmed tibials cover a multitude of patient specific needs by mating with the *NexGen* Knee



CR, CRA, PS, L-PS and L-CCK articular surfaces. The proposed fluted stemmed tibial component shares many features with the *NexGen* Knee stemmed tibials discussed above. It is the same in these respects:

- Length of the stem
- Angle of the stem relative to the distal plate surface
- Position of the cylindrical portion of the stem in the anterior/posterior direction
- Stem extension locking taper design
- Articular surface locking mechanism
- Minimum taper wall thickness
- Depth of the cement mantle pockets in the distal plate surface, size offerings, and material.

The primary difference between the proposed fluted stemmed tibial components and the cleared stemmed tibial component involves the stem base shape. The proposed design uses flutes like the *Insall/Burstein*<sup>®</sup> Knee predicate design. The stem base shape has a posterior slope similar to the *Insall/Burstein* Knee. The stem base has a flute on both the lateral and medial edges which provide channels to direct cement flow from the distal tip to the proximal surface of the cut tibial during insertion, thus, enhancing cement fixation. These flutes give the implant its name. The cleared stemmed tibial component ribs have been replaced by integral flared supports at the base of the stem.

- 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 was submitted in the 510(k) for fatigue strength.

RA07601K.510

---

\**Insall/Burstein* trademark of The Hospital for Special Surgery