

K963700

Summary of Safety and Effectiveness  
for

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**Metagen High Tibial Osteotomy System**

This safety and effectiveness summary for the Metagen High Tibial Osteotomy System is provided as required per Section 513(i)(3) of the Food, Drug and Cosmetic Act.

**1. Submitter :**

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**2. Trade Name:**

Metagen High Tibial Osteotomy System

**Common Name:**

Fracture Fixation System

**Classification Name:**

Single/ multiple component metallic bone fixation appliances and accessories  
(888.3030)

**3. Predicate or legally marketed devices which are substantially equivalent:**

- NexGen Osteotomy System ( Zimmer )
- Natural Knee Family High Tibial Osteotomy System ( Intermedics Orthopedics )
- High Tibial Osteotomy System ( Richards )
- L-buttress, T-buttress and T-plates ( Synthes )
- ECT Internal Fracture Fixation System ( Zimmer )
- Improved Geibel Blade Plates ( Link America Inc. )
- Osteo Auto-Compression Plating System ( Smith & Nephew Richards )
- May Anatomical Bone Plates ( Waldemar Link )

**4. Description of the device :**

The High Tibial Osteotomy System is a fracture fixation system used to perform closing wedge osteotomies. It consists of L-plates, cortical and cancellous bone screws, and offset staples.

**Materials:** The devices are manufactured from CoCrMo ( cast or Wrought ), Ti-6Al-4V, and 316 LVM stainless steel per ASTM standards.

**Function:** The system functions to provide immediate stability and temporary fixation during the natural healing process following osteotomy.

**5. Intended Use:**

The Metagen High Tibial Osteotomy System consists of single use devices, intended to be used for the fixation of fractures of the proximal or distal end of long bones, or to stabilize the fracture site during the healing process following surgical procedures that involve cutting the bone, such as tibial osteotomies.

Tibial osteotomy is indicated in young, active patients with painful unicompartmental osteoarthritis associated with varus deformity of no more than 11 degrees, and for deformity incident to rheumatoid arthritis and trauma in selected cases.

**6. Comparison of the technological characteristics of the device to predicate and legally marketed devices :**

There are no significant differences between the Metagen High Tibial Osteotomy System and the systems currently being marketed which would adversely affect the use of the product. It is substantially equivalent to these other devices in design, function, material and intended use.