

Summary of Safety and Effectiveness TriMax Nail System

Substantial Equivalence Information

K964163

The TriMax Nail System is similar to the following systems:

1. ZMS Intramedullary Fixation System (Zimmer)
2. Grosse & Kempf Locking Nail (Howmedica)
3. Retrograde Femoral Nail (Biomet)
4. Aim Titanium Supracondylar Nail (Ace)
5. Alta Nail (Howmedica)
6. Femoral Nail System (Synthes)

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All of the devices listed above are similar in design to the TriMax Nail System. The safety and effectiveness of the TriMax Nail System is based on the long history of use of these devices in the market place.

Device Description

The TriMax Nail System includes femoral nails and screws. All components are manufactured from stainless steel.

Indications for Use

Femoral/recon antegrade nails and retrograde nails are indicated for shaft fractures including severely comminuted, spiral, large oblique and segmental fractures; nonunions and malunions; bone lengthening/shortening; femur reconstruction following tumor resection and grafting; fractures in osteoporotic bone; severely comminuted shaft fractures; pathologic fractures, pseudoarthrosis, failed osteosynthesis; closed supracondylar fractures; and prophylactic nailing of impending pathologic fractures.

Additional indications for the femoral/recon antegrade include: subtrochanteric fractures with lesser trochanteric involvement; ipsilateral femoral shaft/neck fractures.

Additional indications for retrograde nails include: severely comminuted supracondylar fractures with or without difficult intra-articular extension, fractures that require opening the knee joint to stabilize the femoral condylar segment. Also, fractures above total knee implants.

The TriMax Nail System is intended to be removed upon fracture healing.

Mechanical Testing

Mechanical testing was performed on the system and all of the test results indicate that the TriMax Nail System is capable of withstanding normal *in vivo* loading without failure.