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Summary of Safety and Effectiveness

- **Submitted By**

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- **Date**

December 12, 1996

- **Trade Name**

Intramedullary Nail System

- **Common Name**

Intramedullary Rod

- **Classification Name**

Intramedullary Fixation Rod

- **Predicate Devices**

- Kuntscher Nail, manufactured by Zimmer, Inc.
- Russell-Taylor Intramedullary Nail, manufactured by Smith and Nephew Richards, Inc.



- Supracondylar Nail, manufactured by Zimmer, Inc., K962561, cleared September 25, 1996

- **Device Description**

The Intramedullary Nail System is a series of cannulated intramedullary rods and interlocking screws for use in fixation of long bone fractures. Included in the system are femoral, tibial and humeral nails in varying diameters and lengths. The design of the nail includes four longitudinal flutes along the length of the nail. The larger sized nails have a sawcut over the majority of the length of the nail to aid in insertion. The distal tip of the nail is conical in shape and tapered. All nails include proximal and distal holes for the insertion of interlocking screws. The nails can be used in either the locked or unlocked mode and can be inserted with or without prior reaming of the medullary canal. The nails and screws are manufactured from stainless steel. The nails are inserted using a closed technique.

- **Intended Use**

The intended use of the Intramedullary Nail System is as follows:

Femoral and Tibial Nails

The Intramedullary Nail System femoral and tibial nails are indicated for use in fixation of femoral fractures including subtrochanteric, intertrochanteric, comminuted or segmental fractures, as well as fractures with bone loss, proximal and distal fractures, and nonunions.

Humeral Nail

The humeral Nail is indicated for comminuted fractures, segmental fractures, fractures with bone loss proximal and distal fractures, as well as nonunions, delayed unions, pathological fractures, floating elbow, nerve lesion, and multiple trauma injuries

- **Performance Data**

The Intramedullary Nail System design was tested for bending strength/stiffness and static torsional strength using the ASTM Standard F 383, "Standard Practice for Static Bend and Torsion Testing of Intramedullary Rods." The results showed significant bending strength for all nail diameters. On a size-per-size basis, the Intramedullary System nails are comparable in strength to the predicate device.

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