



zimmer

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**Summary of Safety and Effectiveness
Supracondylar Intramedullary Nail**

- **Submitted by**

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- **Prepared by**

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- **Date**

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- **Trade Name**

Supracondylar Intramedullary Nail

- **Common Name**

Intramedullary Rod

- **Classification Name**

21 CFR 888.3040, Smooth or Threaded Metallic Bone Fixation Fastener



- **Predicate Devices**

- Intramedullary Supracondylar Nail, marketed by Smith & Nephew Richards, Inc.
- AIM Supracondylar Nail, marketed by Ace Orthopedic Manufacturing Company

- **Device Description**

The Supracondylar Nail is a cannulated rod designed to be inserted through the condylar notch in order to fix fractures of the femur. The nail is available in 9 through 13 mm diameters with varying lengths. Each nail contains multiple distal and proximal holes/slots for insertion of locking screws with a cone-shaped head for ease of insertion. The nail is fluted for revascularization. Longer length nails are curved. The holes/slots accept cortical screws for locking of the nail.

- **Intended Use**

The Supracondylar Nail is intended for use in fixation of various types of fractures of the supracondylar or distal region of the femur as well as for proximal fractures in conjunction with supracondylar fractures.

- **Performance Data**

The Supracondylar Nail was tested in four-point bend testing for bending strength and bending rigidity. Results showed significant bending strength and bending rigidity for all nail diameters and designs. Slotted nails demonstrated a reduction in bending strength and bending rigidity. The Supracondylar Nail testing results were compared to predicate devices in terms of design and material, indicating superior strength capabilities for the Zimmer Supracondylar Nail.

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