

**ACUMED™**

K 963026

*Quality Orthopaedic Instruments and Implants***Enclosure D - 510(k) Summary****OCT 28 1996**

This summary regarding 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.93.

The Acumed Retrograde Humeral Nail is an intramedullary rod which addresses humeral fractures. The nail is 8 mm in diameter and is available in lengths of 200 mm, 220 mm, 240 mm, 260 mm, 280 mm, and 300 mm. It is used in conjunction with 3.5 mm interlocking screws.

The Acumed Retrograde Humeral Nail is manufactured from titanium per ASTM F 136. This device is provided pre-sterile. Sterility is achieved by gamma radiation. Validation of sterility is maintained on site. Sterility level is  $10^{-6}$ . Information regarding implantation, packaging, and labeling have been provided.

The Acumed Retrograde Humeral Nail is similar to Smith & Nephew Richards' Russell-Taylor Humeral Interlocking Nail in design, function, indications, and surgical technique and is expected to perform as well as similar devices.