

**ACUMED™**

K963118

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

OCT 10 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 2.7mm Extremity Bone Screw is intended for fracture and osteotomy fixation of the upper and lower extremities. This screw is not intended for usage in the spine and is not for use with any available bone plates, washers, etc. This screw is available in lengths of 12mm, 14mm, 16mm, 18mm, 20mm, 22mm, and 24mm. The screw is driven by a conventional 2.5mm hex head. Hex dimensions are in accordance with ASTM F 543. The Extremity Screw is manufactured from a titanium alloy per ASTM F 136 and is provided non-sterile. On file at Acumed is test data which shows that the screw can be successfully steam sterilized under specific process parameters which will obtain a resulting SAL of  $10^{-6}$ . As the screw is provided non-sterile, packaging information is not provided.

The 2.7mm Extremity Bone Screw is similar to Synthes' 3mm Cannulated Screw System in design, function, indications, and surgical technique and is expected to perform as well as similar devices.