

DEC 9 1996

**Enclosure D - 510(k) Summary**

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 Tension Band Pin is used in conjunction with orthopedic wire to address malleolar, patella, and olecranon fracture fixation in tension band wiring procedures. This device is not intended for usage in the spine. This device has a diameter of .0625" and is available in lengths of 35mm, 45mm, and 55mm. The Acumed Tension Band Pin is manufactured from 316L stainless steel and is provided pre-sterile. Sterility is achieved by a minimum dose of 2.5 megarads of gamma radiation. Validation of sterility is maintained on site. Sterility level is  $10^{-6}$ . Information regarding packaging and labeling have been provided.

The Acumed Tension Band Pin is similar to the Acumed Fixation Pin and the Howmedica Kirschner Wire in material and design. Like Howmedica's Kirschner Wire, the Acumed Tension Band Pin is intended to be used in tension band wiring procedures addressing malleolar, patella, and olecranon fractures.

Based on the similarities between the Acumed Tension Band Pin and both the Acumed Fixation Pin and Howmedica Kirschner Wire, the safety and effectiveness is expected to be similar to the Acumed Fixation Pin and Howmedica Kirschner Wire.