

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 Supracondylar Nail is an intramedullary rod which addresses supracondylar fractures. The nail is available in six different sizes with diameters of 11 mm, 12 mm, and 13 mm and lengths of 150 mm and 220 mm. The nail is used in conjunction with 5 mm interlocking screws.

The Acumed Supracondylar 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 Supracondylar Nail is similar to Smith & Nephew Richards' Intramedullary Supracondylar Nail System in design, function, indications, and surgical technique and is expected to perform as well as similar devices.