

Enclosure D - 510(k) Summary**K960651****MAY - 3 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 Wire Crimp Sleeve is a block with two holes to be used with commonly used cerclage wire. The cerclage wire is passed around the bone, passed through the crimp block, and crimped in a manner identical to the Osteo-Clage Cerclage Cable System and similar to the Howmedica Dall-Miles Cable System. The only difference being the use of wire instead of cable. It is intended for use in general orthopedic repairs wherever cerclage wire is indicated.

The sleeve is manufactured from titanium per ASTM F 136. It is intended for use with titanium or cobalt chromium cerclage wire.

Information regarding implantation, packaging, and labeling have been provided.

This medical device is identical except for material type to the Acumed Cerclage Wire Crimp (K931246). Both the Acumed Cerclage Wire Crimp and the Richards Orthopedic Cable System are manufactured from titanium. In addition, the Acumed Cerclage Wire Crimp may be found substantially equivalent to the Osteo-Clage Cerclage Cable System and the Howmedica Dall-Miles Cable System, is safe and effective, and is expected to perform as well as similar devices.

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