



ACUMED™

Quality Orthopaedic Instruments and Implants

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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510(k) Premarket Notification Database

Device Classification Name	Cerclage, Fixation
510(K) Number	K960651
Regulation Number	888.3010
Device Name	CERCLAGE WIRE CRIMP BLOCK
Applicant	ACU-MED, INC. 10950 Sw 5th, Suite 170 Beaveton, OR 97005
Contact	Shari L Jeffers
Classification Product Code	<u>JDQ</u>
Date Received	02/15/1996
Decision Date	05/03/1996
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	Orthopedic
Review Advisory Committee	Orthopedic
Statement/Summary/Purged Status	Summary Only
Summary	<u>Summary</u>
Type	Traditional
Reviewed By Third Party	No
Expedited Review	No

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