

MAY 22 1996

K961283

510(k) Summary

Proprietary Name: Dall-Miles Homogeneous Vitallium® Cable

Common Name: Bone Fixation Cerclage

Classification Name and Reference: Bone Fixation Cerclage  
21 CFR 888.3010

Proposed Regulatory Class: Class II  
Device Product Code: OR(87) JDQ

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Date Summary Prepared: 4-2-96

This submission describes a modification in intended use of the previously released Dall-Miles Homogeneous Cable (K945294). The original Homogeneous cable is intended to be used for spinal wiring, trochanter reattachment, sternotomy applications, and trauma surgery of the shoulder, elbow, knee, hip, or ankle. Indications for the stabilization of bone graft material and for fracture fixation when used in conjunction with bone plates and screws have been added.

There have been no changes in the design, materials, manufacturing, or operational principles of the Dall-Miles Cable.

Substantial equivalence of the additional indications is based on equivalence in intended use to Howmedica's Dall-Miles Suture/Beaded Cable (K953818), Smith & Nephew Richards' Ries Cable System (K875156), and Depuy's Control Cable System (K934557). Each of the named devices are currently marketed for stabilization of bone graft and fracture fixation.