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K961369

510(k) Summary

Proprietary Name: Dall-Miles Stainless Steel Beaded 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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The Dall-Miles Stainless Steel Beaded Cable is a modification of the existing stainless steel cable. A bead is formed on one end of the cable by melting it with an electron beam. This modification allows the cable to be used with a one-sided Tensioner in those applications where a conventional two-sided Tensioner will not fit.

The Dall-Miles Beaded Cable is intended to be used for spinal wiring, sternotomy applications, cerclage procedures, and trauma surgery of the shoulder, elbow, knee, hip, or ankle. In addition, these cables may be used for supplementary fixation when used with bone plates and screws and for the stabilization of bone graft material.

The substantial equivalence of the Beaded Cable is based on the equivalence in intended use, materials, design, operational principles, and indications and contraindications to Howmedica's Dall-Miles Trochanter Cable Grip System (K844068 & K900926) and Dall-Miles Suture/Beaded Cable (K953818), Smith & Nephew Richards' Ries Cable System (K875156), and Depuy's Control Cable System (K934557).