

510(k) Summary of Safety and Effectiveness

K955306

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Proprietary Name: Omega+ Compression Screw System

Common Name: Compression Screw System

APR - 8 1996

Classification Name and Reference: 21 CFR 888.3030  
Single/multiple component metallic bone fixation appliances  
and accessories

Proposed Regulatory Class: Class II

Device Product Code: KTT OR(87)

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The Omega+ Compression Screw System consists of a series of lag screws, proximal hip sideplates, supracondylar side plates, and a compression screw designed to be used in the temporary stabilization of fractures of the proximal femur (intracapsular or intertrochanteric), and/or distal third of the femur (supracondylar area). These components were previously released under K850886, K872223, K922295, and K930156. These components are now made available in sterile packaging. It is Howmedica's intention to market these products both sterile and non-sterile.

Directions for one recommended sterilization technique are included in the labeling for the device. There is no change in intended use, design, material, method of manufacture, or surgical technique for the device.