

APR -3 1987

K970713

Summary of Safety and Effectiveness Compass Universal Hinge

Substantial Equivalence Information

The Compass Universal Hinge is similar to Smith & Nephew's Ilizarov External Fixator and Howmedica's Dynamic Joint Distractor. All of these devices use external fixation to treat joint contracture or fractures and diseases that may lead to joint contracture. The Compass Universal Hinge represents improvements that enhance user convenience.

Device Description

The Compass Universal Hinge is a device used with external fixation devices for the indications listed previously. The Compass Universal Hinge is applied to bones on both sides of a joint to provide active and passive motion of the joint and to restore loss of range of motion due to contracture.

Indications for Use

The Compass Universal Hinge is a line extension to the Ilizarov external fixation system. It is used in conjunction with the Ilizarov system to treat joint contractures and to restore mobility and function of a joint that has become stiff due to contracture or traumatic injury. The Compass Universal Hinge construct is indicated to treat post-traumatic joint contracture which has resulted in the loss of range of motion, and fractures and disease which generally may result in joint contracture or loss of range of motion.