

510(K) Summary of
Safety and Effectiveness

R960014

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Product: Classification Name: Single/multiple component metallic bone fixation appliances and accessories - (21 CFR 88.3030)
Common Name: External Fixation System
Trade/Proprietary Name: Practifix External Fixation System

Substantially Equivalent Products Hex-Fix External Fixation by Smith and Nephew Richards
Day External Fixation by DePuy
AP/ASIF External Fixation System by Synthes

Description The product consists of AISI 316L stainless steel pins inserted above and below the fracture site. The carbon-fiber tubes in combination with pin clamps act to hold the transfixation pins at the desired angle and position. Bar-bar clamps are used to combine additional carbon fiber tubes in the desired configuration

Intended Use: This product is intended for use as a clamping mechanism between a group of percutaneous Schanz type pins and connecting rods. A minimum of four of these clamps combined with percutaneous pins and connecting rods would be used to externally bridge a fracture or non-union of a long-bone to provide a more stable environment for soft tissue and/or bone healing to occur.

Indications for use include: fracture fixation(open and closed); pseudarthrosis or long bones (both congenital and acquired); limb lengthening by epiphyseal or metaphyseal distraction; correction of bony or soft tissue deformities; correction of osteotomies; and correction of bony or soft tissue defects.

Comparison to Substantial Equivalent Products: All made of the same types of materials, equivalent in function and design.