

K970751

**Summary of Safety and Effectiveness
Heidelberg External Fixator**

APR 16 1997

Substantial Equivalence Information

The Heidelberg External Fixator is substantially equivalent to the following:

1. Hex-Fix Field Fixator--K953397
2. Orthofix External Fixator--K802814
3. Ilizarov External Fixator System--K870961

All of the devices listed above have similar indications for use, similar materials composition, and similar design. The safety and effectiveness of external fixators is based on the long history of use of these devices in the market place.

Device Description

The Heidelberg External Fixator is a modular unilateral, extensible device used for the indications listed previously. Components are made of aluminum, stainless steel, cobalt alloy, brass, and nylon which are similar to materials used in other unilateral fixators.

Indications for Use

Indications for the Heidelberg Fixator include: fracture fixation (open and closed); pseudoarthrosis or nonunion of long bones; limb lengthening, correction of bony or soft tissue deformity; correction of segmental bony or soft tissue defects; and joint arthrodesis.