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Attachment B: Summary of Safety and Effectiveness Information [510(k) Summary]

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Device: Synthes Mini External Fixator is compared to the Howmedica Mini Hoffmann External Fixation System.

The Synthes Mini External Fixator stabilizes and provides treatment for fractures of the hand and foot. Synthes Mini External Fixator includes the following components: Threaded Kirschner Wires, Wire-to-Rod and Rod-to-Rod Clamps, Rods and an Angled Connecting Bar. It is anticipated that the most common use of the device would be as follows:

1. A K-wire is inserted into the proximal and distal fracture with the help of a soft tissue protector.
2. Slide one clamp over each K-wire; slide rod through both clamps.
3. After the fracture is repositioned, securely tighten the nuts for the K-wire and the rod.
4. Place the two remaining K-wires through the two clamp openings.
5. Tighten all clamp nuts.
6. Cut K-wires.

The wires are manufactured from stainless steel; the clamps and angled connecting bar from various grades of stainless steel, the rods from carbon fiber reinforced epoxy.

The Howmedica Mini Hoffmann External Fixation System is also intended for immediate reduction and stabilization of fractures of the hand, wrist, foot and maxillofacial area. It is manufactured from stainless steel.

Based on the results of the mechanical testing, Synthes Mini External Fixator provides fixation that is at least equivalent to or stiffer than the Howmedica Mini Hoffmann External Fixation System.