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510(k) SUMMARY FOR THE X FIX™ DynaFix® Mini External Fixation System

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The EBI X FIX™ DynaFix® Mini External Fixation System is a unilateral external fixation device intended for use in the treatment of bone conditions including leg lengthening, osteotomies, arthrodesis, fracture fixation, and other bone conditions amenable to treatment by use of the external fixation modality. External fixators are recommended for Class II by the Orthopedic Panel (Single/Multiple Component Metallic Bone Fixation Appliance, 21 CFR 888.3030).

The EBI X FIX™ DynaFix® Mini External Fixation System is substantially equivalent* to the Orthofix® Mini Fixator and Orthofix® Mini Lengthener (Orthofix® S.R.L., Verona Italy) the Synthes Mini External Fixator (Synthes, USA) and the Hoffman Mini External Fixator (Howmedica, Inc.).

The EBI X FIX™ DynaFix® Mini External Fixation System consists of fixator components and bone screws. The fixator frame consists of fixator rails which are connected by a central component. The fixator frame attaches to the bone via bone screws which penetrate the patient's skin. The fixator frame secures to the shanks of the bone screws with bone screw clamps. The EBI X FIX™ DynaFix® Mini External Fixation System is capable of providing physicians with capability to lengthen. The EBI X FIX™ DynaFix® Mini External Fixation System frame components are composed of aluminum alloy, titanium alloy and stainless steel. The EBI X FIX™ DynaFix® Mini External Fixation System bone screws are made of 316L stainless steel.

Comparative testing of the EBI X FIX™ DynaFix® Mini External Fixation System and the Orthofix® Mini Fixator and Mini Lengthener was performed. The testing included static and fatigue testing. The results demonstrate that in general, the EBI X FIX™ DynaFix® Mini External Fixation System has greater mechanical strength than the Orthofix® Mini Fixator and Mini Lengthener.

In summary, the results of the static and fatigue testing and the comparison of the systems' intended uses, components and designs demonstrate that the EBI X FIX™ DynaFix® Mini External Fixation System is substantially equivalent to the Orthofix® Mini Fixator and Orthofix® Mini Lengthener, the Synthes Mini External Fixator and the Hoffman Mini External Fixator.



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* Any statement made in conjunction with this submission regarding a determination of substantial equivalence to any other product is intended only to relate to whether the product can be lawfully marketed without pre-market approval or reclassification and is not intended to be interpreted as an admission or any other type of evidence in patent infringement litigation. [Establishment Registration and Premarket Notification Procedures, Final Regulation, Preamble, August 23, 1977 42 FR 42520 (Docket No. 76N-0355)]