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510(k) Summary of Safety & Effectiveness

This 510(k) Summary of Safety and Effectiveness for the EBI X FIX™ DynaFix™ System and EBI DFS™ Distal Radius Fixator is provided as required per Section 513(I)(3) of the Food, Drug and Cosmetic Act.

1. **Submitter:** Electro-Biology, Inc.
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2. **Proprietary Name:** EBI X FIX™ DynaFix™ System - SC Bone Screws
EBI DFS™ Distal Radius Fixator - SC Bone Screws
- Common Name:** External Fixation Bone Screws
- Classification Name:** Single/Multiple Component Metallic Bone Fixation Appliances and Accessories (888.3030)

3. **Predicate or legally marketed devices that are substantially equivalent:**

- EBI X FIX™ DynaFix™ System and DFS™ Distal Radius Fixator Bone Screws
- Vitaphore SilverFoam Wound Dressing
- Genetic Laboratories E-Z DERM™ Temporary Skin Substitute with Silver
- Arrow Antimicrobial Multi-Lumen Central Venous Catheter
- Vitaphore Pin Protection Device

4. **Description of the device:** The bone screws have a tapered thread diameter and are available in a variety of diameters and lengths in both cortical and cancellous thread patterns. The screws will be available with and without the additional proprietary silver coating which has been shown to significantly reduce bacterial colonization of the surface, and will be sold sterile and nonsterile.

Intended Use: The EBI X FIX DynaFix System is intended for 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. The EBI DFS™ Distal Radius Fixator is intended for use in upper extremity applications for the reduction, alignment and stabilization of intra-articular and extra-articular fractures, corrective osteotomies, and soft tissue deformities.

5. **Materials:** The SC bone screws are manufactured from stainless steel, 316L per ASTM F138. The silver coating is applied by a proprietary process according to Device Master File MAF-480.
6. **Comparison of the technological characteristics of the device to predicate devices:** There are no significant differences between the SC bone screws and other currently marketed bone screws. The addition of the silver coating will not adversely affect the use of the bone screws. The coated screws underwent biocompatibility, fatigue, and direct inoculation testing. They are substantially equivalent* to the predicate devices in design and function.

*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 Pre-market Notification Procedures, Final Regulation, Preamble, August 23, 1977, FR 42520 (Docket No. 76N-0355.)]