



*Enhancing Bone Healing
through Applied Science*

MAY - 2 1997

510(k) Summary of Safety & Effectiveness

This 510(k) Summary of Safety and Effectiveness for the EBI SpineLink™ System 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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Date prepared: April 23, 1997

2. **Proprietary Name:** EBI SpineLink™ System
Common Name: Spinal Fixation System for the Noncervical Spine
Classification Names: Spondylolisthesis Spinal Fixation Device System (Proposed)
Spinal Intervertebral Body Fixation Orthosis
Spinal Interlaminar Fixation Orthosis

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

- Webb-Morley Spine System - Electro-Biology, Inc.
- TSRH® Spinal System - Sofamor Danek
- Dyna-Lok® Spine System - Sofamor Danek
- Isola® Spine System - AcroMed Corporation
- KSF Spinal Fixator - Tornier SA
- VSP® Plating System - AcroMed Corporation

4. **Description of the device:** The EBI SpineLink™ System is a spinal fixation device for the noncervical spine consisting of fixed and polydirectional pedicle/sacral screws (available in diameters from 5.5 to 7.5 mm), various types of interconnecting links, lock nuts, and different types of washers.

5. **Intended Use:** The EBI SpineLink™ System, a spinal fixation device for the noncervical spine, is indicated for (a) anterior fixation, (b) posterior hook and sacral/iliac screw fixation and © pedicle screw fixation.

When used as an anterior fixation system or as a posterior hook and sacral/iliac screw fixation system, the system is indicated for nonpedicle spinal applications for the reduction, alignment or stabilization of the thoracic, lumbar and sacral segments of the spine, in cases of degenerative disc disease which is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies, spondylolisthesis, trauma, spinal stenosis, spinal deformities (scoliosis, kyphosis, lordosis), tumor, pseudoarthrosis, or revision of failed fusion attempts.

When used as a pedicle screw fixation system, it is intended for patients: (a) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar - first sacral (L5-S1) vertebral joint; (b) who are receiving fusions using autogenous bone graft only; [®] who are having the device fixed or attached to the lumbar and sacral spine; and (d) who are having the device removed after the development of a solid fusion mass. The screws of the system are limited to L3- S1 or iliac screw fixation with the fusion only at L5-S1.

6. **Materials:** The components of the system are manufactured from Ti-6Al-4V ELI per ASTM F136. The components will be available with and without TiN coating.
7. **Comparison of the technological characteristics of the device to predicate devices:** There are no significant differences between EBI SpineLink™ System and other currently marketed spinal systems. It is substantially equivalent* to the predicate devices in regards to intended use, materials and function. Bench testing comparing the system to a predicate system demonstrated that the device complies with applicable standards and meets all of its functional requirements.

*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.)]