

K955730



Enhancing Bone Healing through Applied Science

Summary of Safety & Effectiveness for EBI Anterior Cervical Spine System

This Safety and Effectiveness Summary for the EBI Anterior Cervical Spine System line extension to include TiN coating is provided as required per Section 513(i)(3) of the Food, Drug and Cosmetic Act.

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2. Proprietary Name: EBI Anterior Cervical Spine System
Common Name: Spinal Fixation System

Classification Name: Spinal Intervertebral Body Fixation Orthosis

3. Predicate or legally marketed devices with TiN coating that are substantially equivalent:

- Cervical Spine Locking Plate distributed by Synthes
Songer Titanium Cable System distributed by Sofamor Danek
Buechel-Pappas Total Hip Replacement System distributed by Endotec, Inc.

4. Description of the device: The EBI Anterior Cervical Spine System consists of spinal implant components and various instruments used during the implantation procedure. The spinal implants consist of plates, screws and locking screws.

Materials: Ti-6Al-4V ELI alloy with or without Titanium nitride coating

5. Intended Use: The EBI Anterior Cervical Spine System is a single use device, intended for anterior cervical spine applications only. Specific indications include the fusion, reduction, alignment or stabilization of the cervical segments of the spine in cases of degenerative disc disease (spondylosis of the cervical spine, cervical spondylotic myelopathy and cervical spondylosis neuropathy), trauma, and tumors.

6. Comparison of the technological characteristics of the device to predicate and legally marketed devices:

There are no significant differences between the TiN coating of the EBI Anterior Cervical Spine System and the other currently marketed TiN coated orthopedic implants which would adversely affect the use of the product. It is substantially equivalent* to these other devices in function, material and chemical composition.

* 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.

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