510(k) Summary

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Trade Names: Seneka II Polyscrew Pedicle Fixation System
Product Class: Class III
Classification: 21 CFR §888.3070 Pedicle Screw Spinal System,
§888.3060 Spinal Intervertebral Body Fixation Orthosis, and
§888.3050 Spinal Interlaminal Fixation Orthosis
Common Name: Pedicle Screw System
Product Codes: NKB, MNI, MNH, KWQ, KWP
Panel Code: 87

Indications for Use:
The Seneka II Polyscrew Pedicle Fixation System is intended for posterior non-cervical fixation as an adjunct to fusion in skeletally mature patients for the following indications: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion. Except for hooks, when used as an anterolateral thoracic/lumbar system the Seneka II Polyscrew Pedicle Fixation System may also be used for the same indications as an adjunct to fusion.

Device Descriptions:
The Seneka II Polyscrew Pedicle Fixation System is comprised of: straight and pre-curved rods, pedicle screw assemblies with both cannulated and non-cannulated screws, reduction screws, domino connectors, offset connectors, hooks and a set screw. Various forms and sizes of these implants are available so that adaptations can be utilized to take into account the unique pathology of individual patients. The Seneka II system can be implanted via the open surgical approach.
Components are made of Ti6Al4V ELI, a titanium based alloy, which complies with ASTM F136, cobalt chrome per ASTM F1537 or CP Titanium per ASTM E2371-13.

Predicate Device(s):
The Seneka II Polyscrew Pedicle Fixation System is substantially equivalent to the primary predicate device which is the Seneka I System from Senecka Spine (K151849). Additional predicate devices include Scien'tx USA Inc. ISOBAR Spinal System (K013444) and the K2M Inc. Everest Spinal System (K151216).

Performance Standards:
The pre-clinical testing performed includes static and dynamic compression bending, and static torsion per ASTM F1717-14.

Technological Characteristics:
Senecka Spine has compared the Seneka II Polyscrew Pedicle Fixation System to the predicate devices in regards to indications for use, materials, function, sizes and mechanical test results. These comparisons demonstrate substantial equivalence to the predicate devices.

Conclusion:
Senecka Spine concludes that the Seneka II Polyscrew Pedicle Fixation System is substantially equivalent to the predicate devices and raises no new questions of safety or effectiveness.