510(k) Summary

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Trade Names: Seneka I Polyscrew Pedicle Fixation System
Product Class: Class III
Classification: 21 CFR §888.3070 Pedicle Screw Spinal System
Common Name: Pedicle Screw System
Product Codes: NKB, MNI, MNH
Panel Code: 87

Indications for Use:
The Seneka I Polyscrew Pedicle Fixation System is intended for posterior, noncervical pedicle fixation as an adjunct to fusion in skeletally mature patients using autograft and/or allograft 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.

Device Descriptions:
The Seneka I 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 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 I 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 I Polyscrew Pedicle Fixation System is substantially the primary predicate device which is the Moss Miami System (DePuy Spine) (K022623). Additional predicate devices include Optima Spinal System (U&I) (K031585) and Xia Spinal System (Stryker) (K001319).

Performance Standards:
The pre-clinical testing performed includes static and dynamic compression bending, and static torsion per ASTM F1717-10.

Technological Characteristics:
Senecka Spine has compared the Seneka I 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 I Polyscrew Pedicle Fixation System is substantially equivalent to the predicate devices and raises no new questions of safety or effectiveness.