510K Summary

Date:	February 12, 2019
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Type of 510(k) submission:	Traditional
Trade name:	Zavation Spinal System
Common name:	Spinal Fixation System
Classification regulation:	888.3070 (NKB) 888.3060 (KWQ)
Device classification:	Class II
Classification Panel:	Orthopedic
Product code:	NKB, KWQ
Basis for submission:	Addition of components

Purpose: The purpose of this submission is to request clearance for additional Zavation Spinal System implants and instruments.

Device Description: The Zavation Spinal System is comprised of polyaxial pedicle screws, rods, and cross connectors. The Zavation Spinal System can be used for single or multiple level fixations. The pedicle screws are available in various lengths and diameters. The rods are available in straight and pre-lordosed (curved) configurations. The system has variable length cross connectors.

Intended Use:
The Zavation Spinal System is a pedicle screw system intended to provide Immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

The Zavation Spinal Systems is also indicated for pedicle screw fixation for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

The Zavation Spinal Systems when used as anterior thoracic/lumbar screw fixation systems, is indicated for degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (fracture and/or dislocation), spinal stenosis, deformities (scoliosis, lordosis and/or kyphosis), tumor, and previous failed fusion (pseudarthrosis).

Materials:
The Zavation Spinal System components are manufactured from titanium alloy (Ti-6Al-4V) as described by ASTM F136.

Predicate Devices:
Zavation Spinal System (K153404) -primary
Depuy Spine Moss Miami Spine System (K955348)
Amedica Corp. Valeo Pedicle Screw Spinal System (K072022)
Altiva Corp. ArcTec Semi-Rigid Plating System (K051044)

Performance Data:
Static compression bending and torsion, and dynamic compression bending were performed according to ASTM F1717 on a worst-case construct. The mechanical test results demonstrated that the Zavation Spinal System performs as well as or better than the predicate devices.

Comparison of Technological Characteristics:
The Zavation Spinal System possesses the same technological characteristics as the predicate devices. These include: basic design (rod based fixation system having polyaxial pedicle screws with various screw and rod diameters and lengths), material (titanium alloy), mechanical safety and performances, and intended use (as described above).

Basis for Substantial Equivalence:
The Zavation Spinal System devices are similar to the predicate systems with respect to technical characteristics, performance and intended use. The information provided within this premarket notification supports substantial equivalence of the subject device to the predicate devices.