

K96-007

Summary of Safety and Effectiveness

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Trade Name: DDS Spinal System

Common Name: Spondylolisthesis Spinal Fixation Device

Classification Name: Unclassified, preamendments device

Description: The DDS Spinal System is a multi-component system consisting of pedicle screws, rods and spacers. The screws are available in five lengths and one diameter; the rods in twelve lengths and the spacers in three thicknesses. The screws are fabricated from titanium alloy (Ti-6Al-4V) that conforms to ASTM F136. The screws have a 6.5 mm thread diameters and are available in five lengths, 35, 40, 45, 50 and 55 mm. The rods are also manufactured from Ti-6Al-4V and are 5 mm in diameter. The rods are available in 12 lengths ranging from 40 mm to 600 mm. Round, smooth spacers of three different heights (2, 4, and 6 mm) slide over the threaded portion of the screw to facilitate implantation of neighboring screws at the same level. The spacers are also made of Ti-6Al-4V.

Intended Use: It is intended for patients with severe spondylolisthesis (Grades 3 and 4) having fusions at the L5-S1 joint using autogenous bone graft, to be fixed/attached to the lumbar and sacral spine. The components are intended to be removed after development of a solid fusion mass. The screws are limited to L3-S1 or iliac screw fixation.

Comparable Features to Predicate Device(s): Features comparable to predicate devices include Moss Spinal System cleared for commercial distribution in K894184.

Test Results: The results of the testing are summarized in the following table and graph.

Test	# of Specimens	Max. Load	Deformation	Stiffness
Axial Compression	5	1403.2±90.6 N	2.69±.61 mm	929.2±117.6 N/mm
Bending	5	24.38±.63 Nm	20.86±1.67 mm	3.07±.53 Nm/mm
Torsion	5	42.30±2.44 Nm	38 degrees	2.58±.09 Nm/deg
Screw Pullout*	16	818.5±341.8 N	NA	NA
Screw Pullout**	5	785.0±289.7 N	NA	NA

*Unembedded specimens

**Wrapped, embedded specimens

