ALPHA™ Posterior Spinal System
510(k) Summary K964275
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I. **Company:** Sofamor Danek USA
1800 Pyramid Place
Memphis, TN 38132
901-396-3133

II. **Proprietary Trade Name:** ALPHA™ Posterior Spinal System

Classification Name: Pedicle Screw Fixation - Spondylolisthesis spinal fixation device system.

III. The ALPHA™ Posterior Spinal System is a spinal rod based system. The ALPHA™ implant components, as well as implant components from the other systems, can be rigidly locked into a variety of configurations, with each construct being tailor-made for the individual case. Implant components comprising the ALPHA system and those components from other Sofamor Danek spinal systems which can be used with the ALPHA™ Posterior Spinal System are listed in the following table. Please note that while the set screws can be used on both size rods, all of the other components are rod-size specific.

Component	5.5mm Diameter Rod	6.35mm Diameter Rod
Rods:		
TSRH® Rods		✓
GDLH™ Rods	✓	
ALPHA™ Rod		✓
Screws:		
ALPHA™ Screws 5.5mm, 6.5mm, 7.5mm diameter	✓	✓
Connectors and Cross Connectors:		
CD HORIZON™ M-10 Break-Off Set Screw	✓	✓
ALPHA™ M-10 Break-Off Set Screw	✓	✓
CD HORIZON™ Low Profile MULTI-SPAN™ CROSSLINK® Plates	✓	✓
ALPHA™ Low Profile MULTI-SPAN™ CROSSLINK® Plates	✓	✓
TSRH® Low Profile CROSSLINK® Offset Plates	✓	✓
TSRH® Low Profile CROSSLINK® Plates	✓	✓
TSRH® CROSSLINK® Plate Set Screws	✓	✓

IV. The ALPHA™ Posterior Spinal Spinal System is intended to provide temporary stabilization and to help augment the development of a solid spinal fusion. The system is intended only patients (a) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar – first sacral (L5-S1) vertebral joint; (b) who are receiving fusions using autogenous bone graft only; (c) who are having the device fixed or attached to the lumbar and sacral spine (L3 and below); and (d) who are having the device removed after the development of a solid fusion mass.

NOTA BENE: The ALPHA™ Posterior Spinal System is limited to non-cervical use. All implant components of the ALPHA™ Posterior Spinal System are intended for posterior spinal fixation. The ALPHA™ Posterior Spinal System is intended only for patients: (a) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar – first sacral (L5-S1) vertebral joint; (b) who are receiving fusions using autogenous bone graft only; (c) who are having the device fixed or attached to the lumbar and sacral spine; and (d) who are having the device removed after the development of a solid fusion mass. The ALPHA™ screws are indicated only for insertion no higher than L3 and not lower than the sacrum. CD HORIZON™ Low Profile MULTI-SPAN™ CROSSLINK® plates, ALPHA™ Low Profile MULTI-SPAN™ CROSSLINK® plates, TSRH® Low Profile CROSSLINK® plates, and TSRH® Low Profile CROSSLINK® Offset plates are intended for posterior thoracic, lumbar, and/or sacral use only.

V. Mechanical test data were supplied in support of the ALPHA™ Posterior Spinal System 510(k) notification. The ALPHA™ Posterior Spinal System was declared to be substantially equivalent to several commercially available devices.