

**K961633**  
**CD HORIZON™ Spinal System**  
**510(k) Summary**  
**November, 1996**

**I. Company:** Sofamor Danek USA  
 1800 Pyramid Place  
 Memphis, TN 38132  
 901-396-3133

DEC - 5 1996

**II. Proprietary Trade Name:** CD HORIZON™ Spinal System

**Classification Name:** Pedicle Screw Fixation - Spondylolisthesis spinal fixation device system. Otherwise, spinal interlaminar fixation orthosis.

**III.** The CD HORIZON™ Spinal System is a spinal rod based system. The CD HORIZON™ implant components, as well as the stainless steel 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 CD HORIZON™ and those components from other stainless steel Sofamor Danek spinal systems which can be used with the CD HORIZON™ Spinal System are listed in the following table. Please note that while some implants are identified for use on both size rods, some of these are designed for specific rod diameter.

Component	5.5mm Diameter Rod	6.35mm Diameter Rod
<b>Rods:</b>		
TSRH® Rods		✓
GDLH™ Rods	✓	
LIBERTY™ Rods		✓
CD HORIZON™ Rod		✓
<b>Hooks:</b>		
CD HORIZON™ Hooks	✓	✓
<b>Screws/Bolts:</b>		
CD HORIZON™ Screws 5.5mm, 6.5mm, 7.5mm diameter	✓	✓
TSRH® Variable Angle Screws 5.5mm, 6.5mm, 7.5mm diameter	✓	✓
DYNA-LOK® Bolts 6.5mm, 7.0mm, 7.5mm, 8.5mm diameter	✓	✓
LIBERTY™ Screws Closed-5.5mm, 6.5mm, 7.5mm diameter		✓
Closed w/10° Oblique Canal-6.5mm, 7.5mm diameter		✓
Closed w/15° Oblique Canal-6.5mm, 7.5mm diameter		✓
Open-5.5mm, 6.5mm, 7.5mm diameter		✓
CCD™ Screw for Sacral Block, 7.0mm diameter	✓	✓
CCD™ Conical Fixation Screws, 7.0mm diameter	✓	✓

Component	5.5mm Diameter Rod	6.35mm Diameter Rod
<b>Connectors and Cross Connectors:</b>		
CD HORIZON™ DTT No. 4 Connectors	✓	✓
CD HORIZON™ Dominos	✓	✓
CD HORIZON™ Axial Connectors	✓	✓
CD HORIZON™ Sacral Fixation Device	✓	✓
CD HORIZON™ C-rings	✓	✓
CD HORIZON™ Low Profile MULTI-SPAN™ CROSSLINK® Plates	✓	✓
TSRH® Low Profile CROSSLINK® Offset Plates	✓	✓
TSRH® Low Profile CROSSLINK® Plates	✓	✓
TSRH® CROSSLINK® Plates	✓	✓
TSRH® Top Tightening Variable Angle T-Bolts, Variable Angle, and Eyebolt Connectors	✓	✓
TSRH® Lateral Offset Plates	✓	✓
TSRH® Rod/Bolt Connectors	✓	✓
TSRH® Variable Angle Lateral Offset Plates	✓	✓
TSRH® Variable Angle CROSSLINK® Plates	✓	✓
TSRH® Fixed CROSSLINK® Plates	✓	✓
GDLH™ CROSSLINK® Bars	✓	
GDLH™ Rod/Bolt Connectors	✓	✓
LIBERTY™ Lateral Connectors		✓
LIBERTY™ Open Implant Closure Saddle and Set Screw		✓
CD HORIZON™, GDLH™, and TSRH® Set Screws and Fasteners	✓	✓

IV. The CD HORIZON™ Spinal System is intended to provide temporary stabilization and to help augment the development of a solid spinal fusion. Except for situations using pedicle screws in 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, the specific indications for the CD HORIZON™ Spinal System are the following:

1. Degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies).
2. Pseudoarthrosis
3. Stenosis
4. Spondylolisthesis
5. Spinal deformities: scoliosis, kyphosis, and lordosis
6. Fracture
7. Unsuccessful previous attempts at spinal fusion
8. Tumor resection

The CD HORIZON™ Spinal System is intended for use only in the thoracic, lumbar, and/or sacral levels of the posterior spine. The CD HORIZON™ Spinal System is limited to non-cervical use. The CD HORIZON™ Screws, TSRH® Variable Angle Screws, LIBERTY™ screws, and/or DYNA-LOK® bolts, when used as pedicle screws with the CD HORIZON™ 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. When used for pedicle screw fixation as described above, the screws are indicated

only for insertion no higher than L3 and not lower than the sacrum. Otherwise the CD HORIZON™ screws, TSRH™ Variable Angle Screws, LIBERTY™ screws, and/or DYNA-LOK™ bolts, when used with the CD HORIZON™ Spinal System, are intended for sacral/iliac attachment only. The CCD™ Screw for Sacral Block and CCD™ Conical Fixation Screws are intended for sacral/iliac attachment only. All of the CD HORIZON™ hooks are intended for thoracic and/or lumbar attachment only. GDLH™ CROSSLINK™ Bars, CD HORIZON™ Low Profile CROSSLINK™ plates, and TSRH™ CROSSLINK™ plates are intended for posterior thoracic, lumbar, and/or sacral use only.

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

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