

LIBERTY™ Anterior Spinal System

510(k) Summary

K965193

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

II. **Proprietary Trade Name:** LIBERTY™ Anterior Spinal System

Classification Name: Spinal intervertebral body fixation orthosis.

III. The LIBERTY™ Anterior Spinal System consists of the following implants components:

Component	Stainless Steel	Titanium Alloy	Commercially Pure Titanium
Rods:			
LIBERTY™ Rods, 6.35mm diameter	✓		
TSRH® Rods, 6.35mm diameter	✓	✓	
CD HORIZON™ Knurled Rod, 6.35mm diameter		✓	
CD HORIZON™ Rod, 6.35mm diameter			✓
Screws:			
LIBERTY™ Closed Screws-5.5mm, 6.5mm, 7.5mm diameter	✓		
LIBERTY™ Closed Screws-6.5mm, 7.5mm diameter		✓	
LIBERTY™ Closed Screw w/10° Oblique Canal-6.5mm, 7.5mm diameter	✓		
LIBERTY™ Closed Screw w/15° Oblique Canal-6.5mm, 7.5mm diameter	✓		
LIBERTY™ Open Screw-5.5mm, 6.5mm, 7.5mm diameter	✓		
Connectors and Cross Connectors:			
LIBERTY™ 12-32 Break-Off Set Screw	✓	✓	
LIBERTY™ Open Implant Closure Saddle	✓		✓
TSRH® Single Hole Staples	✓		
TSRH® Two Hole Offset Staples, Left and Right	✓	✓	
TSRH® Washer	✓	✓	
TSRH® Low Profile CROSSLINK® Offset Plate	✓	✓	
TSRH® Low Profile CROSSLINK® Plate, 0.625 in length	✓	✓	
TSRH® Low Profile CROSSLINK® Plate Set Screws	✓	✓	

The LIBERTY™ Anterior Spinal System implant components are fabricated from ASTM F138 (or its ISO equivalent) stainless steel or from ASTM F136 (or its ISO equivalent) titanium alloy. In addition, one of the CD HORIZON spinal rods which may be used with the LIBERTY™ Anterior Spinal System and the TSRH® Single Hole Anterior Staples are fabricated from commercially pure titanium conforming to ASTM F67 or its ISO equivalent. Titanium implants are not to be used with stainless steel implant components in a spinal construct. A LIBERTY anterior construct may involve either a single rod or two rods. The implant components may be sold sterile or non-sterile. Instrumentation is also available to facilitate implantation of the device components.

IV. The LIBERTY™ Anterior Spinal System is intended to assist in temporarily stabilizing the thoracic and/or lumbar spine until fracture repair or a solid spinal fusion develops. The specific indications for the LIBERTY™ Anterior 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, lordosis, kyphosis
6. Fracture
7. Unsuccessful previous attempts at spinal fusion
8. Tumor resection

All components of the LIBERTY™ Anterior Spinal System are intended to be fixed/attached to the anterolateral spine by screws/staples in the thoracic and/or lumbar areas only.

WARNING: This device system is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

V. Mechanical test data were supplied or referenced in support of the LIBERTY™ Anterior Spinal System 510(k) notification. The LIBERTY™ Anterior Spinal System was declared to be substantially equivalent to other commercially available devices.