

MAY - 8, 1997

**Attachment 7**  
**REVISED 510(K) SUMMARY**

K96 5224

**Summary of Safety and Effectiveness**

**Thorocolumbar Spinal System**

The Thorocolumbar Spinal System consists of single use devices designed to aid in the surgical correction of several types of spinal conditions by providing stabilization until a solid spinal fusion develops.

When used as a pedicle screw system, the Thorocolumbar Spinal System when used in constructs with screws or spinal bolts placed in the pedicle are intended only for: grades 3 or 4 spondylolisthesis at the fifth lumbar-first sacral vertebral (L5-S1) joint: who are receiving fusion using autogenous bone graft only; who are having the device fixed or attached to the lumbar and sacral spine; and who are having the device removed after the development of solid fusion.

When used as a posterior hook and sacral/ilic screw fixation system only, the Thorocolumbar Spinal System is indicated for:

Scoliotic, lordotic, or kyphotic deformities  
ddd ((defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)  
pseudarthrosis  
stenosis  
spondylolisthesis (grade 1 or 2)  
fracture  
tumor resection

As a posterior system, it is limited to **non-cervical posterior use** with the levels of posterior screw fixation from L3-S1.

As an anterolateral spinal system the indications are for anterior stabilization of levels T10 to L5 of the spine following: degenerative disc disease (defined above), tumor resection, spondylolisthesis, spondylolysis, fracture, pseudoarthrosis, and multi-operated back; and to correct lordotic and kyphotic spinal deformities.

The levels of anterolateral use are T10-L5.

Testing of the Thorocolumbar Spinal System included comparison to substantially equivalent devices. The testing results were acceptable and the components should perform as well as comparable systems in clinical usage.