be used in the treatment of fracture or dislocation of the spine, grades 3 and 4 of spondylolisthesis (a dislocation of the spinal column), and lower back syndrome." (An exclusion of lower back syndrome is addressed below). The class II asti anterior plate-screw-cable fixation devices, "Spinal intervertebral body fixation orthosis," are "used to apply a force to a series of vertebrae to correct 'sway back,' scoliosis (lateral curvature of the spine), or other conditions" (21 CFR 888.3060).

Scoliosis is a three-plane spinal deformity, but should also be considered a growth abnormality and a chronic instability. The predominant feature in scoliosis is a lateral curvature of the thoracic and lumbar vertebrae in the coronal plane, but is also accompanied by sagittal plane and rotational deformities. Untreated severe scoliosis can cause severe cosmetic deformity, degenerative facet joint and intervertebral disc disease, paraplegia, right heart failure, and death, and can compromise pulmonary function.

Spinal fractures and dislocations result in loss of bony or ligamentous integrity that cause spinal instability. Untreated traumatic spinal instability may lead to progressive spinal deformity, nonunion, pain, progressive neurologic deficit, and traumatic spinal stenosis.

Spondylolisthesis, whether degenerative or severe, is generally regarded as a chronic instability caused by loss of the structural integrity of posterior element structures, such as the pars interarticularis, as well as the intervertebral disc. Spondylolisthesis results in a chronic, sometimes progressive, anterior subluxation of the superior vertebra over the inferior vertebra. This may be a result of congenital vertebral anomalies (e.g., deficiency of the facets), acquired defects (e.g., traumatic pars defects, pedicle or facet fractures), metabolic bone diseases (e.g., osteogenesis imperfecta, osteoporosis), or degenerative processes (e.g., degenerative disc disease). Spondylolisthesis may cause severe back and leg pain, postural deformity, gait abnormalities due to hamstring tightness, and progressive neurologic deficits.

FDA believes that, for the purposes of device classification, all of the above indications can be categorized as acute and chronic instabilities and deformities.

Lower back syndrome is an ill-defined disorder and is not considered to be included in the indications of acute and chronic instabilities and deformities. Sway back, an obsolete term for

lordosis, is a congenital or developmental sagittal plane deformity. Although 21 CFR 888.3060 states that the asti device is also indicated for "other conditions" that were not specified, the "other conditions' involve instability or a deformity in which fusion is indicated. Both of these asti devices are used as adjuncts to spinal fusion, providing immobilization and stabilization of the spinal segments while fusion takes place. Except for this ill-defined "lower back syndrome," all these indications constitute acute and chronic instabilities or deformities. The common purpose of the treatment of these clinical entities is to prevent the short-term and long-term sequelae of instability and deformity, such as progressive neurologic deficit, severe pain, severe cosmetic deformity, pulmonary and cardiovascular compromise, and even death.

Acute and chronic instabilities or deformities therefore include scoliosis, fractures, dislocations, and spondylolisthesis, but may also include spinal tumors, pseudarthrosis, as well as kyphotic deformities. An extensive laminectomy for spinal stenosis, foraminal stenosis, or other indications may cause iatrogenic spinal instability by removing critical stabilizing posterior element structures (Refs. 78 and 118). Benign and malignant tumors cause instability of the spine by compromising the structural integrity of the anterior. middle, or posterior columns of the spine (Refs. 31, 94, 114, 118, and 126). Segmental defects or loss of posterior elements following tumor resection require instrumentation and fusion to reestablish spinal stability and prevent neurologic injury. The pathogenesis of kyphosis deformities are fracture, inflammation, tumor, congenital malformation, and laminectomy (Refs. 25, 36, and 118). The goal of treatment is immediate and long-term stability, nerve and cord decompression, and correction of angulation. Pseudarthrosis, or failure to achieve a successful fusion, causes symptomatic instability at the motion segment (Refs. 104, 169, and 202)

FDA believes that sufficient clinical data exist to justify including other indications such as scoliosis, spinal tumors, and failed previous fusion attempts (pseudarthrosis) in the intended use of the pedicle screw spinal system. The medical literature and data from IDE clinical investigations demonstrate that the device can effectively stabilize the spine and adequately maintain spinal alignment while fusion takes place, and provide adequate evidence that the device can safely and effectively treat these

conditions (Ref. 66). FDA believes that the risks associated with the use of pedicle screw spinal systems intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion in the treatment of these acute and chronic instabilities and deformities are similar to those of the commercially available device systems (21 CFR 888.3050 and 888.3060) and that these rates are clinically acceptable (Ref. 66). FDA believes that the clinical data from the IDE clinical investigations and the medical literature adequately support the safety and effectiveness of pedicle screw spinal systems for these additional indications (Ref. 66). Moreover, FDA recognizes that these indications for use are similar to those of commercially available class II spinal fixation devices, such as the spinal interlaminal fixation orthosis classified under 21 CFR 888.3050 and the spinal intervertebral body fixation orthosis classified under 21 CFR 888.3060.

FDA believes the medical literature is also supportive of the use of pedicle screw spinal systems in the treatment of acute and chronic instabilities and deformities. As described above in section III.B. of this document, the rates of clinical complications related to the use of pedicle screw spinal systems in the treatment of acute and chronic instabilities and deformities are comparable to those for existing class II devices in terms of mechanical failures (Refs. 3, 5, 19, 22, 24, 32, 35, 37, 43, 47, 50, 51, 58, 59, 60, 73, 77, 79, 87, 89, 90, 94, 95, 107, 109, 110, 113, 116, 122, 125, 150, 151, 152, 162, 163, 164, 173, 183, 185, 186, 187, 191, 192, 193, and 205) soft tissue injuries (Refs. 25, 26, 27, 37, 46, 47, 49, 60, 74, 106, 112, 113, 126, 127, 147, 153, 183, 185, 187, 191, and 192), pseudarthrosis (Refs. 3, 17, 22, 24, 25, 32, 34, 35, 36, 37, 47, 50, 80, 96, 125, 126, 153, 154, 169, 173, 174, 194, and 205), and reoperation rates (Refs. 50, 51, 60, 74, 86, 119, and 173). The clinical performance is also comparable to existing spinal devices in terms of fusion rates (Refs. 1, 22, 27, 37, 49, 55, 66, 80, 86, 95, 96, 109, 110, 113, 125, 163, 169, 173, 183, 185, 186, 187, 192, 200, 201, and 202), rates of successful pain (Refs. 2, 18, 25, 27, 37, 80, 86, 95, 97, 109, 110, and 147), function (Refs. 51, 109, 119, 147, 173, and 206), and neurological outcomes (Refs. 39, 49, 55, 80, 90, 107, 153, 154, and 164).

FDA also recognizes the unique benefits of pedicle screw spinal systems compared to existing spinal instrumentation systems in the treatment of certain conditions involving severe instability or deformity. The rigid, segmental, threecolumn fixation achieved with pedicle