of acute and chronic instabilities and deformities. Therefore, FDA had strongly recommended that the study design be limited to degenerative spondylolisthesis and spinal fracture in order to produce a more meaningful investigation (Ref. 66). These entities were well-recognized and easily definable diagnoses with established radiographic findings, clinical symptomatology, surgical indications, and treatment outcomes. These two diagnoses were expected to yield homogeneous patient groups in terms of recognized prognostic variables. More importantly, these diagnostic groups were recognized to be mechanically demanding and clinically challenging situations that would rigorously test the device. The fracture group, which included fractures and fracturedislocations, represented the extreme of spinal instability, and was often accompanied by neurologic deficit, deformity, pain, and severe functional loss. The degenerative spondylolisthesis group represented chronic instability with deformity from degenerative disease

FDA believes that the following special controls, in combination with the general controls applicable under the act, would provide reasonable assurance of the safety and effectiveness of pedicle screw spinal systems:

(1) Compliance with materials standards, such as ASTM F136, F138, and F1314 (serve to control risks of implant breakage, particulate debris, and metal toxicity); (2) Compliance with mechanical testing standards, such as ASTM PS-5-94, (serves to control risks of implant breakage, loss of fixation, loss of alignment, and loss of reduction); (3) Compliance with biocompatibility testing standards, such as "Tripartite Biocompatibility Guidance for Medical Devices" (9/86) and International Standards Organization (ISO) 10993-1 (serve to control biocompatibility concerns, such as metal toxicity and long-term theoretical risks of carcinogenicity); and (4) Compliance with special labeling requirements (serve to control risks such as nerve root or spinal cord injury, dural tears, vascular injury, visceral injury, pedicle fracture, vertebral body penetration, pseudarthrosis, and loss of fixation and alignment, by adequately warning physicians of potential risks related to the use of the device). For example, the following labeling would be required:

Warning: The safety and effectiveness of pedicle screw spinal systems have not been determined for spinal conditions other than those with significant mechanical instability or deformity requiring fusion with instrumentation. These include significant mechanical instability secondary to spondylolisthesis, vertebral fractures and dislocations; scoliosis, kyphosis, spinal tumors, and pseudarthrosis resulting from previously unsuccessful fusion attempts.

Warning: Implantation of pedicle screw spinal systems is a technically demanding surgical procedure with a significant potential risk of serious injury to patients. This procedure should only be performed by surgeons with adequate training and experience in both the specific surgical technique and use of the specific products to be implanted.

(5) Conduction of postmarket surveillance (PMS) studies for pedicle screw spine systems as a mechanism to address issues related to device specific design differences, surgical techniques, and device usage. Because complications most frequently occur intraoperatively or early postoperatively, yet important common complications occur late postoperatively, a potential PMS study design might include the first 1000 subjects evaluated for intraoperative and early complications and the first 100 subjects evaluated for a minimum of 2 years for late complications.

The agency invites comments on special controls, including labeling statements, which are appropriate to mitigate the risks from use of these devices as they are proposed to be reclassified.

B. Indications for Use

Spinal instability is defined in terms of real or potential neural dysfunction as measured by the degree of structural damage to the vertebral column. Instability has also been defined in terms of fracture patterns or neurologic deficit (Refs. 17 and 58), or excessive sagittal plane translation on flexionextension radiographs or spondylolisthesis (Ref. 19). Spinal deformities include structural deformities, such as scoliosis, kyphosis, lordosis, and severe spondylolisthesis.

Fusion of the thoracic, lumbar, and sacral spine is often necessary in the treatment of disorders that involve instability and deformity. Fusion provides permanent stabilization of the involved unstable motion segments and correction of structural deformities, and prevents the long-term sequelae of these disorders.

Clinically, all entities that require fusion, either to treat acute or chronic instability or to correct a spinal deformity, may be indications for the use of adjunctive spinal instrumentation. Spinal instrumentation, including anterior instrumentation systems and posterior hook-rod, sublaminar wire-rod, or pedicle screw-based instrumentation systems, is used as an adjunct to fusion by immobilizing and stabilizing the involved vertebral motion segments until fusion occurs. Successful fusion is dependent on the maintenance of spinal alignment and elimination of motion at the fusion site. Spinal instrumentation systems are simply contrivances that promote fusion by providing immobilization and stabilization between intervertebral motion segments.

Mechanically, the stabilization of the involved motion segments and maintenance of alignment are accomplished by all types of spinal instrumentation systems by attaching anchors to vertical supporting members (Ref. 13). The posterior hook-rod and posterior sublaminar wire-rod device systems provide mechanical stabilization of the vertebrae with longitudinal rods attached to the laminae or spinous processes via hooks or wires. The anterior plate-screw-cable fixation devices provide stabilization with longitudinal plates or cables attached to the vertebral bodies via screws placed anteriorly or laterally. Similarly, pedicle screw spinal systems provide stabilization of vertebrae with longitudinal plates or rods attached to the vertebral bodies via screws through the pedicles. Mechanical testing has demonstrated that the pedicle screw spinal systems has equivalent or superior mechanical characteristics, such as static and fatigue strength, when compared to asti class II posterior hookrod and anterior plate-screw-cable spinal devices (see section III.A.2. of this document). In addition, the rigidity of the vertebrae instrumented with pedicle screw spinal systems is greater than when instrumented with the other device systems (see section III.A.2. of this document). In vivo studies have demonstrated that the strength of the fusion is directly related to the rigidity of the spinal instrumentation (Ref. 123). Clinical studies also have verified that the rate of successful fusion is related to the rigidity of the spinal instrumentation (Ref. 202).

FDA believes that the indications for use of asti devices, as described in 21 CFR 888.3050 and 888.3060, are comparable to the proposed indications for pedicle screw spinal systems. Currently, the class II asti posterior hook-rod, sublaminar wire-rod, sacral screw-rod, and iliac screw-rod fixation devices, "Spinal interlaminal fixation orthoses," are used to "straighten and immobilize the spine to allow bone grafts to unite and fuse the vertebrae together" (21 CFR 888.3050). The intended use is "primarily in the treatment of scoliosis (a lateral curvature of the spine), but it also may