

surgery with pedicle screw instrumentation gave personal testimonies of their experiences with the device, citing both successes and failures. Several litigation attorneys, representing patients involved in class action lawsuits against spinal implant manufacturers, addressed the Panel with their views. Five spine surgeons gave their professional opinions regarding the usefulness of the pedicle screw device in their practices. Three surgeons representing spinal professional societies presented their societies' viewpoints.

At the conclusion of the July 22, 1994, meeting, the Panel recommended that FDA reclassify the generic type of device from class III into class II when intended for the treatment of degenerative spondylolisthesis and spinal trauma. The Panel recommended further that FDA adopt special controls as deemed necessary by FDA under 513(a)(1)(B) of the act, and that FDA assign a low priority for the establishment of a performance standard for this generic type of device under section 514 of the act (21 U.S.C. 360d).

Since 1986, a number of manufacturers have sought to demonstrate that the pedicle screw spinal system is a preamendments device, that is, that it was commercially available prior to May 28, 1976, the enactment date of the 1976 amendments. In a 510(k) dated December 22, 1994, Sofamor Danek, Inc., provided sufficient evidence of the preamendments commercial distribution of a spinal system that utilized pedicle screws. In a letter to Sofamor Danek, Inc., dated January 20, 1995, FDA acknowledged that sufficient evidence now exists documenting that pedicle screw spinal systems were commercially available prior to May 28, 1976. The preamendments pedicle screw spinal fixation device system consisted of hooks, spinal rods, threaded sacral rods, and pedicle screws connected to the rods with wire. The device was intended only for lumbar and sacral spine fusions using autogenous bone graft in patients with severe spondylolisthesis (grades 3 and 4) with removal of the device after spinal fusion was achieved. On January 20, 1995, the first postamendments pedicle screw spinal system was found to be substantially equivalent to the preamendments device. Based on this new information, FDA has determined that the pedicle screw spinal system is an unclassified preamendments device when indicated for autogenous bone graft fusions of the fifth lumbar vertebra to the sacrum in patients with severe spondylolisthesis (grades 3 and 4) at L₅-

S₁ with removal of the device after fusion has been achieved. In a letter, dated April 3, 1995, FDA asked the Panel to provide its recommendations on the classification of this preamendments device. The Panel unanimously recommended that the preamendments pedicle screw spinal system be classified into class II when intended for autogenous bone graft fusions of the fifth lumbar vertebra to the sacrum in patients with severe spondylolisthesis (grades 3 and 4) at L₅-S₁ with removal of the device after fusion has been achieved.

In this document, FDA is publishing the recommendations of the Panel with respect to classification of the preamendments device and reclassification of the postamendments device. FDA is also proposing to classify both the preamendments and postamendments devices into class II, and to codify them in one regulation.

III. Recommendations of the Orthopedic and Rehabilitation Devices Panel

The Orthopedic and Rehabilitation Devices Panel, an FDA advisory panel, made the following recommendations regarding the classification of the pedicle screw spinal system:

(1) *Identification.* A pedicle screw spinal system is a multiple component device, made of alloys such as 316L stainless steel (Ref. 11), 316LVM stainless steel (Ref. 11), 22Cr-13Ni-5Mn stainless steel (Ref. 12), unalloyed titanium (Ref. 9), and Ti-6Al-4V (Ref. 10), that allows the surgeon to build an implant system to fit the patient's anatomical and physiological requirements. A spinal implant assembly consists of anchors (e.g., bolts, hooks, and screws); interconnection mechanisms incorporating nuts, screws, sleeves, or bolts; longitudinal members (e.g., plates, rods, and plate/rod combinations); and transverse connectors. The device is used primarily in the treatment of acute and chronic instabilities and deformities, such as trauma, tumor, or degenerative spondylolisthesis.

(2) *Classification recommendation.* Class II (special controls). The Panel recommended that the establishment of a performance standard be low priority.

(3) *Summary of reasons for recommendation.* The Orthopedic and Rehabilitation Devices Panel recommended that pedicle screw spinal systems be classified into class II because the Panel believed that general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, but that there is sufficient information

to establish special controls to provide such assurance. The Panel also believed that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device. The Panel believed that public information demonstrates that the risks to health have been characterized and can be controlled. The Panel also believed that the relationship between these risks and the device's performance parameters have been established and are sufficiently understood to assure the safety and effectiveness of the device. Furthermore, the Panel recognized that there exist voluntary standards and test methods with respect to the production of the device.

(4) *Summary of data on which the recommendation is based.* The Orthopedics and Rehabilitation Devices Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and presentations at the open panel meeting. The Panel noted that, based upon clinical data from the Cohort study, IDE clinical investigations, and the literature, pedicle screw spinal systems performed at least equivalent to, and in some instances superior to, currently available class II anterior and posterior spinal fixation devices, as well as to treatments not utilizing internal fixation devices for degenerative spondylolisthesis and trauma.

The Panel noted that, based on the Cohort study, clinical investigations under IDE protocols and studies available from the scientific literature, the use of pedicle screw spinal systems, when intended for the treatment of degenerative spondylolisthesis and spinal trauma, produced statistically significantly higher spinal fusion rates than when no fixation or nonpedicle screw spinal fixation was used. In addition, the Panel believed that these studies demonstrated statistically significant improvements in patients' clinical outcomes in terms of pain, function, and neurologic status. The Panel believed that these studies demonstrated significant technical and clinical advantages from the use of the device (Ref. 66).

According to the Panel, the mechanical testing data presented at the August 20, 1993, panel meeting demonstrated that pedicle screw spinal systems exhibit adequate mechanical strength, rigidity, and fatigue resistance for the expected length of time required to stabilize the spine to allow fusion to occur (Ref. 65).

The Panel concluded that the data presented at the July 22, 1994, panel meeting provided clinical evidence that the device was effective in stabilizing