Potential Benefits of Pedicle Screw Spinal Systems

The number of motion segments in fracture patients that were required to be fused when using pedicle screw fixation has been reported to be half that required when using hook-rod and sublaminar wire-rod instrumentation (Refs. 77, 109, 154, and 203). This reduction in the number of spinal segments fused preserves motion at the adjacent motion segments, particularly at the important caudal levels of the spine. In these same publications, the authors reported that, when using pedicle screw spinal systems, the frequency of disc degeneration at levels adjacent to the fused segments was found to occur at rates comparable to those occurring in hook-rod and sublaminar wire-rod instrumentation

The rigid, segmental, three-column fixation achieved with pedicle screw fixation allowed successful fixation of severely unstable spines in cases of tumor (Refs. 31, 77, 94, and 114), severe fracture-dislocation (Refs. 2, 4, 17, 35, 46, 53, 58, 59, 73, 107, 108, 128, 130, 140, 153, 154, 160, and 178), deformities (Ref. 25), pseudarthrosis (Ref. 104), severe spondylolisthesis (Refs. 27, 77, and 175), and instability following extensive laminectomy (Refs. 113 and 118). Two authors reported that posterior distraction achievable with pedicle screw instrumentation may allow greater fracture reduction and spinal canal decompression, and may improve neurological recovery (Refs. 70 and 203).

## IV. FDA's Tentative Findings

FDA agrees with the Orthopedic and Rehabilitation Devices Panel's recommendation and is proposing that the pedicle screw spinal system intended for the treatment of degenerative spondylolisthesis, severe spondylolisthesis, and spinal trauma be classified into class II. FDA believes that there exists sufficient information to develop special controls which will provide reasonable assurance of the safety and effectiveness of these devices. FDA believes that appropriate special controls should include mechanical testing standards of performance, special labeling requirements, and postmarket surveillance. FDA also believes that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device.

The data demonstrate that the use of pedicle screw-based instrumentation in the treatment of degenerative spondylolisthesis and fractures results in significantly higher fusion rates, improved clinical outcomes, and comparable complication rates when compared with treatment with no instrumentation or with currently available preamendments class II spinal devices (see section III.B. of this document).

The data also demonstrate that the use of pedicle screw-based instrumentation in the treatment of severe spondylolisthesis results in equivalent or higher fusion rates, similar clinical outcomes, and comparable complication rates when compared with treatment with no instrumentation or with currently available preamendments class II spinal devices (Refs. 5, 6, 14, 27, 28, 29, 30, 48, 52, 68, 81, 82, 83, 84, 92, 93, 147, 155, 159, 168, 169, 175, and 188).

V. Summary of Data Upon Which FDA's Findings are Based

## A. Clinical and Mechanical Data

FDA analyzed the medical literature pertaining to pedicle screw spinal systems and presented its findings at the July 22, 1994, advisory panel meeting (Ref. 66). The literature pertaining to the clinical performance of pedicle screw spinal systems is extensive and describes clinical indications for use, descriptions of surgical techniques, definitions of clinical endpoints and outcome variables used to evaluate safety and effectiveness, and descriptions of the types, and estimates of the frequencies, of device-related complications. The literature pertaining to the mechanical characteristics of pedicle screw-based spinal instrumentation is also extensive and provides considerable data on the device materials, strength, and other mechanical characteristics of the device (see section II.A.2. of this document).

Review of publicly released IDE clinical investigation data from annual reports (Ref. 65), as well as data released by the study sponsors (Ref. 66), provided FDA clinical data from controlled investigations on clinical and radiographic outcomes, fusion rates, and device-related complication rates.

Review of the MedWatch and Medical Device Reporting (MDR) data bases, FDA's device problem reporting systems, provided information regarding the types of device-related complications associated with the use of spinal instrumentation devices. The complications associated with pedicle screw spinal systems reported to FDA were comparable to those associated with the use of commercially available class II spinal fixation devices (Ref. 66).

The Cohort study data, submitted to the agency by the Scientific Committee and presented to the panel at the July 22, 1994, meeting, provided data from a large cohort of patients with spinal fusions (Refs. 66 and 201). FDA evaluated the Cohort study and identified a number of shortcomings in the study design. FDA found that the Cohort study design has weaknesses inherent in all retrospective studies, including concerns of possible selection bias; comparability of the treatment groups; differences in the diagnostic inclusion criteria; treatment differences, including differences in surgeon skill and experience, surgical procedures, devices, and postoperative care; differences in outcome measurement and reporting; and the degree of completeness of medical records (Ref. 66). In addition, FDA found that a significant number of cases did not complete the 2-year followup period required for IDE clinical trials and that several issues regarding the pooling of data were not addressed (Ref. 66). However, many of these weaknesses were anticipated in the planning phase of the study and steps were taken to minimize these potential problems.

FDA has determined that, despite its weaknesses, the Cohort study was conducted in a scientifically sound manner (Ref. 66). The investigation provided adequate numbers of cases, followup times, clinical performance data, and complication rate data to permit assessment of the safety and effectiveness of the device. In addition. FDA has determined that the data meet the criteria for valid scientific evidence found in 21 CFR 860.7(c)(2), that is, they are from partially controlled studies, studies and objective trials without matched controls, well-documented case histories conducted by qualified experts, and reports of significant human experience with a marketed device, from which it can fairly and responsibly be concluded by qualified experts that there is reasonable assurance of the safety and effectiveness of a device under its conditions of use. Under this regulation, the evidence may vary according to the characteristics of the device, its conditions of use, the existence and adequacy of warnings and other restrictions, and the extent of experience with its use.

FDA recognizes that the design and intent of the Cohort study was to investigate two demanding clinical situations rather than merely two diagnostic groups. The investigation of this device for these two diagnostic entities constituted a "worst case scenario." FDA has concluded that these entities represented the extremes