spinal tumors. Such intended uses encompass both degenerative spondylolisthesis and spinal trauma. In addition, FDA is proposing to classify the preamendments pedicle screw spinal system intended for the treatment of severe spondylolisthesis into class II, in accordance with section 513(d) of the act and 21 CFR 860.84.

FDA is proposing to place the pedicle screw spinal system in class II because it believes that there is sufficient information to establish special controls to provide reasonable assurance of its safety and effectiveness.

Two categories of spinal fixation implants that were in commercial distribution prior to the date of enactment of the amendments have been classified into class II: Posterior hook-rod fixation devices (classification: 21 CFR 888.3050, Spinal interlaminal fixation orthosis) and anterior platescrew-cable fixation devices (classification: 21 CFR 888.3060, Spinal intervertebral body fixation orthosis). In addition, bone plates and screws were placed into class II when intended for general orthopedic use in long bone fracture fixation (classifications: 21 CFR 888.3030, Single/multiple component metallic bone fixation appliances and accessories). However, bone plates and screws were considered postamendments class III devices when incorporated into pedicle screw spinal systems. This proposal does not affect the classification of those devices.

Pedicle screw spinal systems include a broad category of multiple component implants. The first premarket notification submission (510(k)) for a multiple component device system intended for attachment to the spine via the pedicles of the vertebrae was submitted to FDA for marketing clearance in 1984. FDA determined that the device was not substantially equivalent to the following devices: (1) Single/multiple component metallic bone fixation appliances and accessories intended for long bone fracture fixation; and (2) interlaminal spinal fixation device systems that attached to the spine via sublaminar wiring or interlaminal hooks. FDA's decision was based on the fact that the sponsor had not established that there was a preamendments device incorporating pedicle screw components and that the device posed potential risks not exhibited by other spinal fixation systems, such as a greater chance of neurological deficit due to imprecise screw placement or the event of a screw failure; pedicle fracture during placement of screws; soft tissue damage or inadequate fusion due to bending or fracture of device components; and

greater risk of pseudarthrosis due to instability of the device design. Because they were not found to be substantially equivalent to a preamendments device, these systems were automatically classified into class III under section 513(f)(1) of the act.

In 1985, in response to another 510(k), FDA determined that the interlaminal spinal fixation device (i.e., rods and hooks and/or sublaminar wires) with screws attached to the sacrum was substantially equivalent to the class II interlaminal spinal fixation device with hooks supported on a rod threaded into the iliac crests (21 CFR 888.3050). However, when the same device was fixed to the pedicles, FDA determined that the device was not substantially equivalent to the spinal interlaminal fixation orthosis (21 CFR 888.3050) and is therefore a postamendments class III device.

Clinical investigations of pedicle screw spinal systems under investigational device exemption (IDE) protocols began in 1985. No premarket approval application has been brought before the advisory panel or approved to date.

By mid-1992, FDA discovered that the use of pedicle screw spinal systems outside of approved IDE studies was widespread, and that pedicle screw fixation was considered to be the standard of care by the surgical community. To obtain guidance in resolving this issue in the best interests of the public health, FDA convened an advisory panel meeting on August 20, 1993, to review the available information pertaining to the safety and effectiveness of the device. Mechanical testing data, summaries of clinical studies conducted under FDA-approved IDE protocols, and presentations by experts in the field were presented to the Panel. After reviewing the information, the Panel concluded that pedicle screw spinal devices appear to be safe and effective when used as adjuncts to spinal fusion procedures, but that additional clinical information was needed in order to determine what regulatory controls should be required to provide reasonable assurance of their safety and effectiveness.

During a February 1993 meeting, FDA requested the orthopedic professional societies and spinal implant manufacturers to submit to FDA all available valid scientific data on the performance of pedicle screw spinal devices. In response, the Spinal Implant Manufacturers Group (SIMG) was formed to provide the financing for a nationwide study of the pedicle screw device. The SIMG consists of representatives from the American

Academy of Orthopedic Surgeons, the Scoliosis Research Society, the North American Spine Society, the American Association of Neurological Surgeons, the Congress of Neurological Surgeons, and 25 manufacturers of spinal implant systems. The Scientific Committee of the SIMG, consisting of surgeons and scientists, was formed specifically to develop and implement a uniform research protocol to gather clinical experience from the use of the device. FDA also provided extensive input into the design of the study protocol. With the permission of individual IDE sponsors, FDA's scientific staff provided the Scientific Committee with information about current IDE clinical investigations, the types of diagnostic groups being studied, the patient inclusion and exclusion criteria utilized, the outcome variables under study, and insight into the types of problems encountered with these studies. FDA also made recommendations regarding the feasibility of various study designs, including an historical cohort model. Finally, FDA provided the Scientific Committee with extensive advice regarding statistical analysis of the data, validation of data, reduction of study bias, and sample size calculations. The Scientific Committee then conducted a nationwide historical cohort study according to this research protocol.

The Panel met on August 20, 1993, and July 22, 1994, in open public meetings to discuss the postamendments pedicle screw spinal system. At the July 22, 1994, meeting, new information was presented to the Panel by FDA and others, and recommendations were solicited from the Panel regarding the classification of pedicle screw spinal systems. During this meeting, the Panel heard testimony from FDA, the medical and scientific communities, manufacturers, and the public regarding the safety and effectiveness of the device. At this meeting, the SIMG presented clinical data from its nationwide "Historical Cohort Study of Pedicle Screw Fixation in Thoracic, Lumbar, and Sacral Spinal Fusions" (Cohort study). FDA presented a comprehensive review of the medical literature, an analysis of the Cohort study conducted by the SIMG, and a summary of the clinical data that had been released by IDE sponsors. Presentations of two meta-analyses of the literature pertaining to the clinical performance of the device were given by spinal surgeons. In addition, 38 persons gave presentations during the public comment portion of the panel meeting. Patients who had had spinal fusion