Issued in Kansas City, Missouri, on September 26, 1995. Henry A. Armstrong, *Acting Manager, Small Airplane Directorate, Aircraft Certification Service.* [FR Doc. 95–24640 Filed 10–3–95; 8:45 am] BILLING CODE 4910–13–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 888

[Docket No. 95N-0176]

Orthopedic Devices: Classification, Reclassification, and Codification of Pedicle Screw Spinal Systems

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to classify certain unclassified preamendments pedicle screw spinal systems into class II (special controls), and to reclassify certain postamendments pedicle screw spinal systems from class III (premarket approval) to class II. FDA is also issuing for public comment the recommendations of the Orthopedic and Rehabilitation Devices Panel (the Panel) concerning the classification of pedicle screw spinal systems, and the agency's tentative findings on the Panel's recommendations. After considering any public comments on the Panel's recommendations and FDA's proposed classification, in addition to any other relevant information that bears on this action, FDA will publish a final regulation classifying the device. This action is being taken because the agency believes that there is sufficient information to establish special controls that will provide reasonable assurance of its safety and effectiveness.

DATES: Written comments by January 2, 1996.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Mark N. Melkerson, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2036.

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- I. Highlights of the Proposal

FDA is issuing for public comment several recommendations of the Panel concerning the classification of pedicle screw spinal systems. The Panel recommended that FDA classify into class II the unclassified preamendments pedicle screw spinal system intended for the treatment of severe spondylolisthesis (grades 3 and 4) of the fifth lumbar vertebra in patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine with removal of the implant after the attainment of a solid fusion. The Panel also recommended that FDA reclassify the postamendments pedicle screw spinal system intended for degenerative spondylolisthesis and spinal trauma from class III to class II. For all other indications, pedicle screw spinal systems are considered postamendments class III devices for which premarket approval is required. The Panel made its recommendations after reviewing information presented at two public meetings on August 20, 1993 and July 23, 1994, and after reviewing information which was solicited in response to an April 3, 1995, letter. FDA is also issuing for public comment its tentative findings on the Panel's recommendations. FDA is proposing to expand the intended uses of the device identified by the Panel to include pedicle screw spinal systems intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion in the treatment of acute and chronic instabilities and deformities, including spondylolisthesis, fractures and dislocations, scoliosis, kyphosis, and spinal tumors. Finally, FDA is proposing to codify the classification of both the preamendments and the postamendments device in one regulation. Comments received in response to this proposed rule, along with other relevant information that the agency may obtain, will be relied upon by the agency in formulating a final position on each of the foregoing issues and provide the basis for a final agency regulation.

II. Background

The Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) and the Safe Medical Devices Act of 1990 (the SMDA) established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories are as follows: Class I, general controls; class II, special controls; and class III, premarket approval. Devices that were in commercial distribution before May 28. 1976 (the date of enactment of the amendments) are classified under section 513 of the act (21 U.S.C. 360c) after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. A device that is first offered for commercial distribution after May 28, 1976, and is substantially equivalent to a device classified under this scheme, is also classified into the same class as the device to which it is substantially equivalent.

A device that was not in commercial distribution prior to May 28, 1976, and that is not substantially equivalent to a preamendments device, is classified by statute into class III without any FDA rulemaking proceedings. The agency determines whether new devices are substantially equivalent to previously offered devices by means of the premarket notification procedure in section 510(k) of the act (21 U.S.C. 360(k)) and part 807 of the regulations (21 CFR part 807).

The pedicle screw spinal system intended for indications other than severe spondylolisthesis is a postamendment device classified into class III under section 513 (f) of the act (21 U.S.C. 360c(f)). In accordance with sections 513(e) and (f) of the act and 21 CFR 860.134, based on new information with respect to the device, FDA, on its own initiative, is proposing to reclassify this device from class III to class II when intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion in the treatment of acute and chronic instabilities and deformities, including spondylolisthesis, fractures and dislocations, scoliosis, kyphosis, and