

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 888**

**[Docket No. 95N-0176]**

DUB

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**Orthopedic Devices: Classification and Reclassification of Pedicle Screw Spinal Systems; Technical Amendment**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule; technical amendment.

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**SUMMARY:** The Food and Drug Administration (FDA) is correcting a final rule that classified certain previously unclassified preamendments pedicle screw spinal systems and reclassified certain postamendments pedicle screw spinal systems. The agency is correcting the rule to include an intended use that was inadvertently omitted from the codified language in the rule. In addition, the agency is correcting the rule to clarify that, when intended for certain uses, the device is a preamendments, not a postamendments, device. These actions are being taken under the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments), the Safe Medical Devices Act of 1990 (SMDA), and the Food and Drug Administration Modernization Act of 1997 (FDAMA).

**DATES:** This rule is effective [*insert date 30 days after date of publication in the Federal Register*].

**FOR FURTHER INFORMATION CONTACT:** Aric D. Kaiser, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2036.

**SUPPLEMENTARY INFORMATION:**

ch9931

NFR-2

## **I. Background**

In the **Federal Register** of July 27, 1998 (63 FR 40025), FDA published a final rule classifying certain previously unclassified preamendments pedicle screw spinal systems and reclassifying certain postamendments pedicle screw spinal systems. Following publication of the rule, the agency discovered that the rule contained several errors.

## **II. Corrections to the Rule**

### *A. Severe Spondylolisthesis (Grades 3 and 4) at L5-S1 in Skeletally Mature Patients*

FDA inadvertently omitted one intended use from the codified language in the rule. This use, for which the device was being classified into class II, is treatment of severe spondylolisthesis (grades 3 and 4) of the L5–S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having the implants attached to the lumbar and sacral spine with removal of the implants after attainment of a solid fusion. This omission from the codification was a typographical error. As described in the preamble to the rule, the Orthopedics and Rehabilitation Devices Advisory Panel (the Panel) recommended classifying the device into class II when intended for this use, and the agency had determined that class II was the appropriate class. In fact, the summary of the final rule included this intended use in the list of intended uses for which the device was being classified into class II. The agency is correcting the rule, therefore, to include treatment of severe spondylolisthesis (grades 3 and 4) of the L5–S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having the implants attached to the lumbar and sacral spine with removal of the implants after attainment of solid fusion in the list of class II intended uses for the device.

*B. In Skeletally Mature Patients: Degenerative Spondylolisthesis With Objective Evidence of Neurologic Impairment; Fracture; Dislocation; Failed Previous Fusion (Pseudarthrosis); Degenerative Disc Disease; and Spondylolisthesis Other Than Either Severe Spondylolisthesis (Grades 3 and 4) at L5–S1 or Degenerative Spondylolisthesis with Objective Evidence of Neurologic Impairment*

In the final rule, FDA described the intended uses listed above as postamendments intended uses. However, on March 20, 1998, prior to publication of the final rule, FDA cleared a premarket notification submission (510(k)) that included preamendments documentation showing that spondylolisthesis (all types and grades), spondylolysis, trauma, failed previous fusions (pseudarthrosis), degenerative disc disease, and degeneration of the facets accompanied by instability in the cervical, thoracic, lumbar and sacral spine (C2–S1) are preamendments intended uses (Ref. 1). The 510(k) submission included affidavits establishing preamendments use from the original device marketer, the device inventor, credible users, and the sponsor of the 510(k). CDRH's Office of Compliance found these documents adequate to establish the preamendments status of this device as a pedicle screw spinal system for specific indications. Consequently, the rule should have stated that for these intended uses, the device was being classified, not reclassified.

FDA acknowledges that the additional preamendments intended uses should have been incorporated into the final rule prior to its publication. If this had been done, the codified language would be as it is below. The agency regrets any inconveniences that this delay in incorporating the additional preamendments intended uses may have caused.

**1. In Skeletally Mature Patients: Degenerative Spondylolisthesis With Objective Evidence of Neurologic Impairment; Fracture; Dislocation; and Failed Previous Fusion (Pseudarthrosis)**

FDA's error in referring to the device when intended to treat degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, or failed previous fusion (pseudarthrosis), as a postamendments, rather than a preamendments, device did not affect the classification into class II under the final rule. The agency intended to classify the device when

intended for these uses into class II. In addition, the requirement that the agency obtain a recommendation from an advisory panel regarding the classification of a preamendments device was met because the Panel considered these intended uses when making its recommendation (Ref. 2). The fact that these are preamendments devices, rather than postamendments devices, intended uses has no impact on either the classification of the device or the premarket submissions required for pedicle screw spinal systems intended for these uses. In addition, no change in the codified language of the rule is necessary to reflect this fact.

## 2. Degenerative Disc Disease and Spondylolisthesis Other Than Either Severe Spondylolisthesis (Grades 3 and 4) at L5–S1 or Degenerative Spondylolisthesis With Objective Evidence of Neurologic Impairment

FDA also described the device when intended to treat degenerative disc disease and spondylolisthesis other than severe spondylolisthesis (grades 3 and 4) at L5–S1 as a postamendments, rather than as a preamendments, device. This error did not affect the classification of the device, when intended for these uses, into class III under the final rule. The agency intended to classify the device when intended for these uses into class III. In addition, the requirement that the agency obtain from an advisory panel a recommendation regarding the classification of a preamendments device was satisfied because the Panel considered these intended uses when making its recommendation (Ref. 2).

However, the agency's error does affect the type of premarket submission required for the device when intended for these uses. Because these are preamendments intended uses, premarket approval applications are not required until the agency issues a final rule under section 515(b) of the act (21 U.S.C. 360e(b)) requiring submission of premarket approval applications. FDA intends to initiate the call for premarket approval applications for the device when intended for these uses in a future document in the **Federal Register**. Until that time, the devices may enter the market after clearance of a premarket notification (510(k)) submission. The agency is correcting the rule accordingly.

*C. Spondylolysis and Degeneration of the Facets Accompanied by Instability in the Thoracic, Lumbar and Sacral Spine; Severe Spondylolisthesis (Grades 3 and 4) at L5–S1 in the Nonskeletally Mature Population; Treatment of Cervical Spondylolisthesis (All Grades and Types); Cervical Spondylolysis; Cervical Degenerative Disc Disease; Degeneration of the Cervical Facets Accompanied by Instability; Cervical Trauma (Fracture and Dislocation); and Revision of Failed Previous Fusion Surgery (Pseudarthrosis) of the Cervical Spine*

On January 20, 1995, the agency cleared a 510(k) that included documentation that use of pedicle screw spinal systems to treat severe spondylolisthesis (grades 3 and 4) at L5–S1 in patients receiving fusion by autogenous bone graft having the implants attached to the lumbar and sacral spine with removal of the implants after attainment of a solid fusion is a preamendments intended use. While the preamendments indication originally described by the agency in the final rule was limited to skeletally mature patients, the preamendments documentation also supports the use of this pedicle screw spinal system for the same intended use in patients who are not skeletally mature (Ref. 3).

In addition, the March 20, 1998, 510(k) clearance described above in section II.B of this document identified a number of intended uses that were not included as part of the final rule, specifically:

(1) Spondylolysis in the thoracic, lumbar and sacral spine;

(2) Degeneration of the facets accompanied by instability in the thoracic, lumbar and sacral spine;

(3) Cervical spondylolisthesis (all grades and types);

(4) Cervical spondylolysis;

(5) Cervical degenerative disc disease;

(6) Degeneration of the cervical facets accompanied by instability;

(7) Cervical trauma (fracture and dislocation); and

(8) Revision of failed previous fusion surgery (pseudarthrosis) of the cervical spine.

Neither the use in nonskeletally mature patients nor the eight intended uses listed above were discussed by the Panel at either its August 20, 1993, or July 23, 1994, meetings or as part of the information they subsequently reviewed. Because they are preamendments intended uses, a panel recommendation is required before they may be classified (21 U.S.C. 360c(c)). FDA intends to seek the recommendation of an advisory panel with respect to classification of the device when intended for these uses at a future Panel meeting. For these intended uses, the device currently is considered an unclassified preamendments device and may enter the market after clearance of a 510(k) submission.

*D. Summary of the Revisions to § 888.3070*

In light of the above, FDA has made the following changes to § 888.3070:

(1) FDA has reorganized the section to simplify the presentation.

(2) FDA has added "severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra" to the intended uses for the class II pedicle screw spinal systems (§ 888.3070(b)(1)). FDA has also added this intended use to the labeling for the special controls.

(3) FDA has changed the intended uses for which pedicle screw spinal systems are in class III from "all other uses" to "when intended to provide immobilization and stabilization of spinal segments in the thoracic, lumbar, and sacral spine as an adjunct to fusion in the treatment of degenerative disc disease and spondylolisthesis other than either severe spondylolisthesis (grades 3 and 4) at L5-S1 or degenerative spondylolisthesis with objective evidence of neurologic impairment" (§ 888.3070(b)(2)).

(4) FDA has amended § 888.3070(c) to state that, for the devices described in paragraph § 888.3070(b)(2), no effective date has been established for submission of a premarket approval application (PMA) or a notice of completion of a product development protocol (PDP). FDA will issue a rule to require PMA's or PDP's for these devices in the future. Until that time, pedicle screws for these intended uses may be marketed through the premarket notification process.

(5) At a future time, and after obtaining a Panel recommendation, FDA will propose a rule to classify the device for the unclassified uses described in section II.C of this document

### **III. References**

The following references have been placed on display in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. These references may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. K970599, Sofamor Danek Townley Pedicle Screw Plating System.
2. Food and Drug Administration Orthopedic and Rehabilitation Devices Advisory Panel Meeting transcripts, Gaithersburg, MD, July 22, 1994.
3. K932029, Sofamor Danek TSRH Spinal System.

### **IV. Environmental Impact**

The agency had determined under 21 CFR 25.30(i) that this final rule is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

### **V. Analysis of Impacts**

FDA has examined the impact of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C 601-612) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Public Law 104-121)), and the Unfunded Mandates Reform Act of 1995 (Public Law 104-4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this rule is consistent with the regulatory philosophy and principles identified in the Executive order.

In addition, this rule is not a significant regulatory action as defined by the Executive order and so is not subject to review under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The only effect of this correction is to delay the requirement for manufacturers of pedicle screw spinal systems intended for certain uses to submit PMA's for these devices until FDA issues a regulation requiring such submissions. Therefore, the agency certifies that this final rule will not have a significant economic impact on a substantial number of small entities. This rule also does not trigger the requirement for a written statement under section 202(a) of the Unfunded Mandates Reform Act because it does not impose a mandate that results in an expenditure of \$100 million or more by State, local, or tribal governments in the aggregate, or by the private sector, in any one year.

#### **List of Subjects in 21 CFR Part 888**

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 888 is amended as follows:

#### **PART 888—ORTHOPEDIC DEVICES**

1. The authority citation for 21 CFR part 888 continues to read as follows:

**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Section 888.3070 is revised to read as follows:

#### **§ 888.3070 Pedicle screw spinal system.**

(a) *Identification.* Pedicle screw spinal systems are multiple component devices, made from a variety of materials, including alloys such as 316L stainless steel, 316LVM stainless steel, 22Cr-13Ni-5Mn stainless steel, Ti-6Al-4V, and unalloyed titanium, that allow the surgeon to build an implant system to fit the patient's anatomical and physiological requirements. Such a spinal implant

assembly consists of a combination of anchors (e.g., bolts, hooks, and/or screws); interconnection mechanisms incorporating nuts, screws, sleeves, or bolts; longitudinal members (e.g., plates, rods, and/or plate/rod combinations); and/or transverse connectors.

(b) *Classification.* (1) Class II (special controls), when intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: severe spondylolisthesis (grades 3 and 4) of the L5–S1 vertebra; degenerative spondylolisthesis with objective evidence of neurologic impairment; fracture; dislocation; scoliosis; kyphosis; spinal tumor; and failed previous fusion (pseudarthrosis). These pedicle screw spinal systems must comply with the following special controls:

(i) Compliance with material standards;

(ii) Compliance with mechanical testing standards;

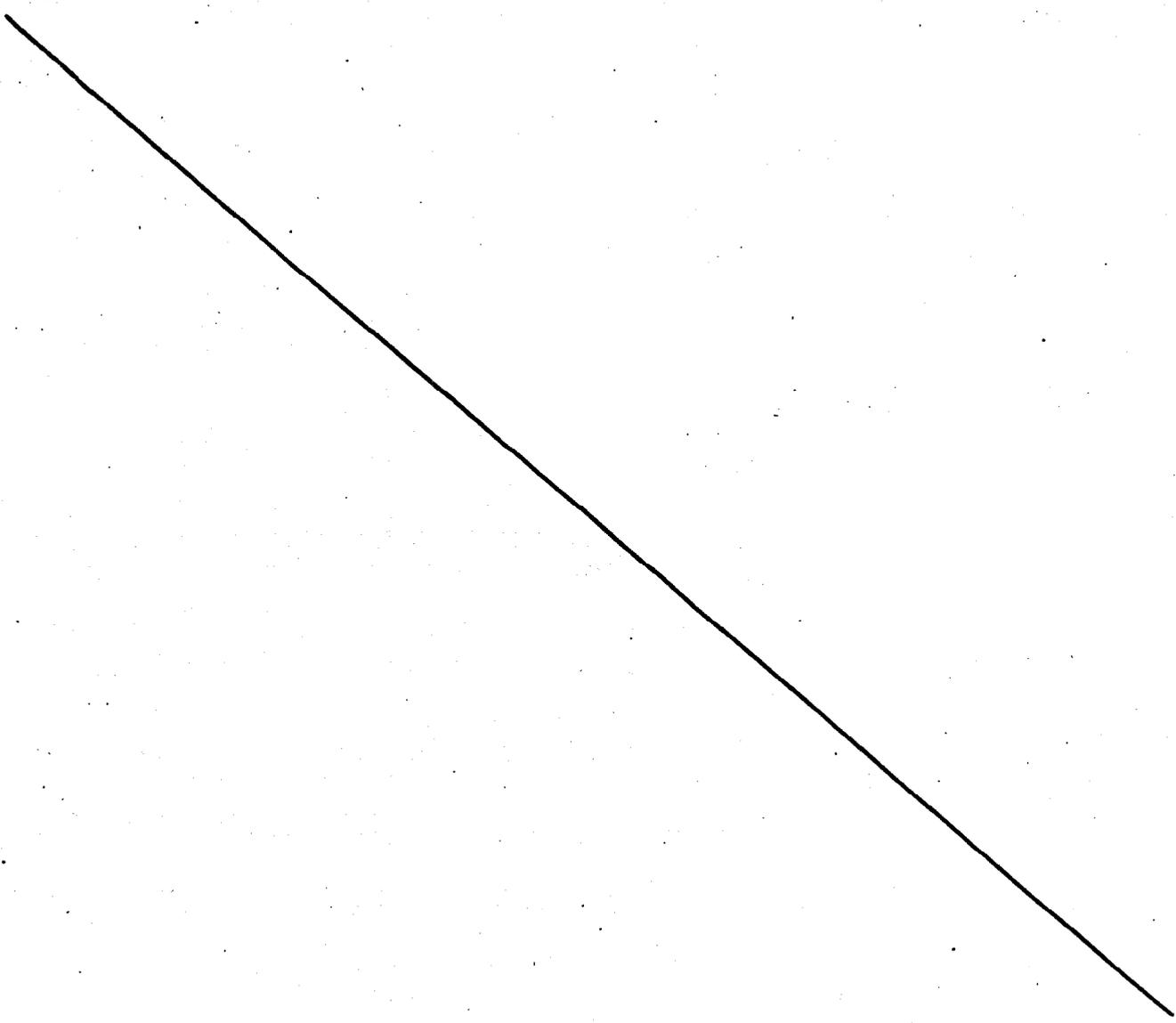
(iii) Compliance with biocompatibility standards; and

(iv) Labeling that contains these two statements in addition to other appropriate labeling information:

“Warning: The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to severe spondylolisthesis (grades 3 and 4) of the L5–S1 vertebra, degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.”

“Precaution: The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.”

(2) Class III (premarket approval), when intended to provide immobilization and stabilization of spinal segments in the thoracic, lumbar, and sacral spine as an adjunct to fusion in the treatment of degenerative disc disease and spondylolisthesis other than either severe spondylolisthesis (grades 3 and 4) at L5-S1 or degenerative spondylolisthesis with objective evidence of neurologic impairment.



(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval for the devices described in paragraph (b)(2) of this section. See § 888.3.

Dated: 5-11-01  
May. 11, 2001.



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Margaret M. Dotzel,  
Associate Commissioner for Policy.

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