

§ 888.3040

§ 888.3040 Smooth or threaded metallic bone fixation fastener.

(a) *Identification.* A smooth or threaded metallic bone fixation fastener is a device intended to be implanted that consists of a stiff wire segment or rod made of alloys, such as cobalt-chromium-molybdenum and stainless steel, and that may be smooth on the outside, fully or partially threaded, straight or U-shaped; and may be either blunt pointed, sharp pointed, or have a formed, slotted head on the end. It may be used for fixation of bone fractures, for bone reconstructions, as a guide pin for insertion of other implants, or it may be implanted through the skin so that a pulling force (traction) may be applied to the skeletal system.

(b) *Classification.* Class II.

§ 888.3050 Spinal interlaminar fixation orthosis.

(a) *Identification.* A spinal interlaminar fixation orthosis is a device intended to be implanted made of an alloy, such as stainless steel, that consists of various hooks and a posteriorly placed compression or distraction rod. The device is implanted, usually across three adjacent vertebrae, to straighten and immobilize the spine to allow bone grafts to unite and fuse the vertebrae together. The device is used primarily in the treatment of scoliosis (a lateral curvature of the spine), but it also may be used in the treatment of fracture or dislocation of the spine, grades 3 and 4 of spondylolisthesis (a dislocation of the spinal column), and lower back syndrome.

(b) *Classification.* Class II.

§ 888.3060 Spinal intervertebral body fixation orthosis.

(a) *Identification.* A spinal intervertebral body fixation orthosis is a device intended to be implanted made of titanium. It consists of various vertebral plates that are punched into each of a series of vertebral bodies. An eye-type screw is inserted in a hole in the center of each of the plates. A braided cable is threaded through each eye-type screw. The cable is tightened with a tension device and it is fastened or crimped at each eye-type screw. The device is used to apply force to a series

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of vertebrae to correct “sway back,” scoliosis (lateral curvature of the spine), or other conditions.

(b) *Classification.* Class II.

§ 888.3070 Pedicle screw spinal system.

(a) *Pedicle screw spinal systems—(1) 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 allows 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. The devices are 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: degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

(2) *Classification.* Class II (special controls). 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 which 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

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.”

(b) *Pedicle screw spinal systems for all other uses*—(1) *Identification*. Pedicle screw spinal systems for all other uses 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 an 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.

(2) *Classification*. Class III (premarket approval).

(c) *Date PMA or notice of completion of a PDP is required*. An approved PMA or a declared completed PDP must be in effect before placing the device in commercial distribution. See § 888.3.

[63 FR 40040, July 27, 1998]

§ 888.3100 Ankle joint metal/composite semi-constrained cemented prosthesis.

(a) *Identification*. An ankle joint metal/composite semi-constrained cemented prosthesis is a device intended to be implanted to replace an ankle joint. The device limits translation and rotation: in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that consist of a talar resurfacing component made of alloys, such as cobalt-chromium-molybdenum, and a tibial resurfacing component fab-

ricated from ultra-high molecular weight polyethylene with carbon fibers composite, and is limited to those prostheses intended for use with bone cement (§ 888.3027).

(b) *Classification*. Class II.

§ 888.3110 Ankle joint metal/polymer semi-constrained cemented prosthesis.

(a) *Identification*. An ankle joint metal/polymer semi-constrained cemented prosthesis is a device intended to be implanted to replace an ankle joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces and has no linkage across-the-joint. This generic type of device includes prostheses that have a talar resurfacing component made of alloys, such as cobalt-chromium-molybdenum, and a tibial resurfacing component made of ultra-high molecular weight polyethylene and is limited to those prostheses intended for use with bone cement (§ 888.3027).

(b) *Classification*. Class II.

§ 888.3120 Ankle joint metal/polymer non-constrained cemented prosthesis.

(a) *Identification*. An ankle joint metal/polymer non-constrained cemented prosthesis is a device intended to be implanted to replace an ankle joint. The device limits minimally (less than normal anatomic constraints) translation in one or more planes. It has no linkage across-the-joint. This generic type of device includes prostheses that have a tibial component made of alloys, such as cobalt-chromium-molybdenum, and a talar component made of ultra-high molecular weight polyethylene, and is limited to those prostheses intended for use with bone cement (§ 888.3027).

(b) *Classification*. Class III.

(c) *Date PMA or notice of completion of a PDP is required*. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any ankle joint metal/polymer non-constrained cemented prosthesis that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996, been found to be