

§ 888.3030

Polymethylmethacrylate (PMMA)
Bone Cement.”

[67 FR 46855, July 17, 2002]

§ 888.3030 Single/multiple component metallic bone fixation appliances and accessories.

(a) *Identification.* Single/multiple component metallic bone fixation appliances and accessories are devices intended to be implanted consisting of one or more metallic components and their metallic fasteners. The devices contain a plate, a nail/plate combination, or a blade/plate combination that are made of alloys, such as cobalt-chromium-molybdenum, stainless steel, and titanium, that are intended to be held in position with fasteners, such as screws and nails, or bolts, nuts, and washers. These devices are used for fixation of fractures of the proximal or distal end of long bones, such as intracapsular, intertrochanteric, inter-cervical, supracondylar, or condylar fractures of the femur; for fusion of a joint; or for surgical procedures that involve cutting a bone. The devices may be implanted or attached through the skin so that a pulling force (traction) may be applied to the skeletal system.

(b) *Classification.* Class II.

§ 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.

21 CFR Ch. I (4–1–10 Edition)

§ 888.3045 Resorbable calcium salt bone void filler device.

(a) *Identification.* A resorbable calcium salt bone void filler device is a resorbable implant intended to fill bony voids or gaps of the extremities, spine, and pelvis that are caused by trauma or surgery and are not intrinsic to the stability of the bony structure.

(b) *Classification.* Class II (special controls). The special control for this device is the FDA guidance document entitled “Class II Special Controls Guidance: Resorbable Calcium Salt Bone Void Filler Device; Guidance for Industry and FDA.” See § 888.1(e) of this chapter for the availability of this guidance.

[68 FR 32636, June 2, 2003]

§ 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 of vertebrae to correct “sway back,”