§ 888.3010 Bone fixation cerclage.

(a) Identification. A bone fixation cerclage is a device intended to be implanted that is made of alloys, such as cobalt–chromium–molybdenum, and that consists of a metallic ribbon or flat sheet or a wire. The device is wrapped around the shaft of a long bone, anchored to the bone with wire or screws, and used in the fixation of fractures.

(b) Classification. Class II.

§ 888.3015 Bone heterograft.

(a) Identification. Bone heterograft is a device intended to be implanted that is made from mature (adult) bovine bones and used to replace human bone following surgery in the cervical region of the spinal column.

(b) Classification. Class III.

(c) Date PMA or notice of completion of a PDP is required. As of May 28, 1976, an approval under section 515 of the act is required before this device may be commercially distributed. See §888.3.

§ 888.3020 Intramedullary fixation rod.

(a) Identification. An intramedullary fixation rod is a device intended to be implanted that consists of a rod made of alloys such as cobalt–chromium–molybdenum and stainless steel. It is inserted into the medullary (bone marrow) canal of long bones for the fixation of fractures.

(b) Classification. Class II.

§ 888.3025 Passive tendon prosthesis.

(a) Identification. A passive tendon prosthesis is a device intended to be implanted made of silicon elastomer or a polyester reinforced medical grade silicone elastomer intended for use in the surgical reconstruction of a flexor tendon of the hand. The device is implanted for a period of 2 to 6 months to aid growth of a new tendon sheath. The device is not intended as a permanent implant nor to function as a replacement for the ligament or tendon nor to function as a scaffold for soft tissue ingrowth.

(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 is made of alloys, such as cobalt–chromium–molybdenum, and that consists of a metallic ribbon or flat sheet or a wire. The device is wrapped around the shaft of a long bone, anchored to the bone with wire or screws, and used in the fixation of fractures.

§ 888.3027 Polymethylmethacrylate (PMMA) bone cement.

(a) Identification. Polymethylmethacrylate (PMMA) bone cement is a device intended to be implanted that is made from methylmethacrylate, polymethylmethacrylate, esters of methacrylic acid, or copolymers containing polymethylmethacrylate and polystyrene. The device is intended for use in arthroplastic procedures of the hip, knee, and other joints for the fixation of polymer or metallic prosthetic implants to living bone.

(b) Classification. Class II (special controls). The special control for this device is the FDA guidance document entitled “Class II Special Controls Guidance Document: Polymethylmethacrylate (PMMA) Bone Cement.”

§ 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, intercervical, 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.
§ 888.3045 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.

§ 888.3046 Spinal interlaminal fixation orthosis.

(a) Identification. A spinal interlaminal 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," scoliosis (lateral curvature of the spine), or other conditions.

(b) Classification. Class II.

§ 888.3050 Spinal intervertebral body fixation orthosis.

(a) Identification. A spinal intervertebral body fixation orthosis is a multiple component device, 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;