Food and Drug Administration, HHS

§ 888.3027 Polymethylmethacrylate (PMMA) bone cement.
(a) Identification. Polymethylmethacrylate (PMMA) bone cement 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.

§ 888.3025 Passive tendon prosthesis.
(a) Identification. A passive tendon prosthesis is a device intended to be implanted made of silicone 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.

§ 888.3020 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.

§ 888.3015 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.

§ 888.3010 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.