§ 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.

Subpart D—Prosthetic Devices

§ 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 II (special controls). The special control for this device is the FDA guidance document entitled “Class II Special Controls Guidance — Bone Grafting.”