Food and Drug Administration, HHS § 888.3660 Shoulder joint metal/polymer semi-constrained cemented prosthesis.

(a) Identification. A shoulder joint metal/polymer semi-constrained cemented prosthesis is a device intended to be implanted to replace a shoulder 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 have a humeral resurfacing component made of alloys, such as cobalt-chromium-molybdenum, and a glenoid 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. The special controls for this device are:

- (1) FDA’s:
  - (ii) “510(k) Sterility Review Guidance of 2/12/90 (K90-1),”
  - (iii) “Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement,”
  - (iv) “Guidance Document for the Preparation of Premarket Notification (510(k)) Application for Orthopedic Devices,” and

- (2) International Organization for Standardization’s (ISO):
  - (iv) ISO 5832-12:1996 “Implants for Surgery—Cemented Metal/Polymer/Bone,”
  - (vi) ISO 6018:1987 “Orthopaedic Implants—General Requirements for Marking, Packaging, and Labeling,” and

- (3) American Society for Testing and Materials (ASTM):
  - (i) F 75–92 “Specification for Cast Cobalt-28 Chromium-6 Molybdenum Alloy for Surgical Implant Material,”
  - (iii) F 799–96 “Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Forgings for Surgical Implants,”
  - (iv) F 1044–95 “Test Method for Shear Testing of Porous Metal Coatings,”
  - (v) F 1108–97 “Specification for Titanium-6 Aluminum-4 Vanadium Alloy Castings for Surgical Implants,”
  - (vi) F 1147–95 “Test Method for Tension Testing of Porous Metal,”
  - (vii) F 1378–97 “Standard Specification for Shoulder Prosthesis,” and


§ 888.3670 Shoulder joint metal/polymer metal nonconstrained or semi-constrained porous-coated uncemented prosthesis.

(a) Identification. A shoulder joint metal/polymer metal nonconstrained or semi-constrained porous-coated uncemented prosthesis is a device intended to be implanted to replace a
§ 888.3680 Shoulder joint. The device limits movement in one or more planes. It has no linkage across-the-joint. This generic type of device includes prostheses that have a humeral component made of alloys such as cobalt-chromium-molybdenum (Co-Cr-Mo) and titanium-aluminum-vanadium (Ti-6Al-4V) alloys, and a glenoid resurfacing component made of ultra-high molecular weight polyethylene, or a combination of an articulating ultra-high molecular weight bearing surface fixed in a metal shell made of alloys such as Co-Cr-Mo and Ti-6Al-4V. The humeral component and glenoid backing have a porous coating made of, in the case of Co-Cr-Mo components, beads of the same alloy or commercially pure titanium powder, and in the case of Ti-6Al-4V components, beads or fibers of commercially pure titanium or Ti-6Al-4V alloy, or commercially pure titanium powder. The porous coating has a volume porosity between 30 and 70 percent, an average pore size between 100 and 1,000 microns, interconnecting porosity, and a porous coating thickness between 500 and 1,500 microns. This generic type of device is designed to achieve biological fixation to bone without the use of bone cement.

(b) Classification. Class II (special controls). The special control for this device is FDA’s “Class II Special Controls Guidance: Shoulder Joint Metal/Polymer/Metal Nonconstrained or Semi-Constrained Porous-Coated Uncemented Prosthesis.”


§ 888.3690 Shoulder joint humeral (hemi-shoulder) metallic un cemented prosthesis.

(a) Identification. A shoulder joint humeral (hemi-shoulder) metallic un cemented prosthesis is a device made of alloys, such as cobalt-chromium-molybdenum. It has an intramedullary stem and is intended to be implanted to replace the articular surface of the proximal end of the humerus and to be fixed without bone cement (§ 888.3027). This device is not intended for biological fixation.

(b) Classification. Class II.

§ 888.3720 Toe joint polymer constrained prosthesis.

(a) Identification. A toe joint polymer constrained prosthesis is a device made of silicone elastomer or polyester reinforced silicone elastomer intended to be implanted to replace the first metatarsophalangeal (big toe) joint. This generic type of device consists of a single flexible across-the-joint component that prevents dislocation in more than one anatomic plane.

(b) Classification. Class II.

§ 888.3730 Toe joint phalangeal (hemi-toe) polymer prosthesis.

(a) Identification. A toe joint phalangeal (hemi-toe) polymer prosthesis is a device made of silicone elastomer intended to be implanted to replace the base of the proximal phalanx of the toe.