§ 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:
   (i) ‘‘Use of International Standard ISO 10993—Biological Evaluation of Medical Devices—Part I: Evaluation and Testing,’’
   (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
   (v) ‘‘Guidance Document for Testing Non-articulating, ‘Mechanically Locked’ Modular Implant Components.’’

(2) International Organization for Standardization’s (ISO):
   (iv) ISO 5833:1992 ‘‘Implants for Surgery—Acrylic Resin Cements,’’
   (vi) ISO 6018:1987 ‘‘Orthopaedic Implants—General Requirements for Marking, Packaging, and Labeling,’’
   (3) American Society for Testing and Materials:
   (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
   (viii) F 1537–94 ‘‘Specification for Wrought Cobalt-28 Chromium-6 Molybdenum Alloy for Surgical Implants.’’