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,''

(v) ''Guidance Document for Testing Non-articulating, 'Mechanically Locked' Modular Implant Components,''

(2) International Organization for Standardization's (ISO):

(i) ISO 5832–3:1996 ''Implants for Surgery—Metallic Materials—Part 3: Wrought Titanium 6-Aluminum 4-Vandium Alloy,''

(ii) ISO 5832–4:1996 ''Implants for Surgery—Metallic Materials—Part 4: Cobalt-Chromium-Molybdenum Casting Alloy,''

(iii) ISO 5832–12:1996 ''Implants for Surgery—Metallic Materials—Part 12: Wrought Cobalt-Chromium-Molybdenum Alloy,''

(iv) ISO 5833:1992 ''Implants for Surgery—Acrylic Resin Cements,''

(v) ISO 5834–2:1998 ''Implants for Surgery—Ultra High Molecular Weight Polyethylene—Part 2: Moulded Forms,''

(vi) ISO 6018:1987 ''Orthopaedic Implants—General Requirements for Marking, Packaging, and Labeling,''

(vii) ISO 9001:1994 ''Quality Systems—Model for Quality Assurance in Design/Development, Production, Installation, and Servicing,'' and

(viii) ISO 14630:1997 ''Non-active Surgical Implants—General Requirements,''

(3) American Society for Testing and Materials':

(i) F 75–92 ''Specification for Cast Cobalt-28 Chromium-6 Molybdenum Alloy for Surgical Implant Material,''

(ii) F 648–98 ''Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants,''

(iii) F 799–96 ''Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Forgings for Surgical Implants,''

(iv) F 981–93 ''Practice for Assessment of Compatibility of Biomaterials (Nonporous) for Surgical Implant with Respect to Effect of Material on Muscle and Bone,''

(v) F 1044–95 ''Test Method for Shear Testing of Porous Metal Coatings,''

(vi) F 1108–97 ''Specification for Titanium-6 Aluminum-4 Vanadium Alloy Castings for Surgical Implants,''

(vii) F 1147–95 ''Test Method for Tension Testing of Porous Metal Coatings, '' and

(viii) F 1537–94 ''Specification for Wrought Cobalt-28 Chromium-6 Molybdenum Alloy for Surgical Implants.''

[65 FR 17147, Mar. 31, 2000]

§ 888.3160 Elbow joint metal/polymer semi-constrained cemented prosthesis.

(a) *Identification.* An elbow joint metal/polymer semi-constrained cemented prosthesis is a device intended to be implanted to replace an elbow 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 consist of a humeral resurfacing component made of alloys, such as cobalt-chromium-molybdenum, and a radial resurfacing component made of ultra-high molecular weight polyethylene. This generic type of device is limited to those prostheses intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class II.

§ 888.3170 Elbow joint radial (hemi-elbow) polymer prosthesis.

(a) *Identification.* An elbow joint radial (hemi-elbow) polymer prosthesis is a device intended to be implanted made of medical grade silicone elastomer used to replace the proximal end of the radius.

(b) *Classification.* Class II.

§ 888.3180 Elbow joint humeral (hemi-elbow) metallic uncemented prosthesis.

(a) *Identification.* An elbow joint humeral (hemi-elbow) metallic uncemented prosthesis is a device intended to be implanted made of alloys, such as cobalt-chromium-molybdenum, that is used to replace the distal end of