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substantially equivalent to a ankle joint metal/polymer non-constrained cemented prosthesis that was in commercial distribution before May 28, 1976. Any other ankle joint metal/polymer non-constrained cemented prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[52 FR 33702, Sept. 4, 1987, as amended at 61 FR 50709, Sept. 27, 1996]

§ 888.3150 Elbow joint metal/polymer constrained cemented prosthesis.

(a) *Identification.* An elbow joint metal/polymer constrained cemented prosthesis is a device intended to be implanted to replace an elbow joint. It is made of alloys, such as cobalt-chromium-molybdenum, or of these alloys and of an ultra-high molecular weight polyethylene bushing. The device prevents dislocation in more than one anatomic plane and consists of two components that are linked together. This generic type of device 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,"

(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: Co-

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balt-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